**Adoption, Health Impact and Cost of Smoke-Free Multi-Unit Housing Policies**

**New**

Supporting Statement

Part A--Justification

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**PART A:** **JUSTIFICATION**

**A.1 Circumstances Making the Collection of Information Necessary**

This is a new Information Collection Request (ICR) to conduct a study of the adoption and implementation of both voluntary and regulatory smoke-free policies in Multi-Unit Housing (MUH) apartment complexes as a method of reducing residents’ exposure to Secondhand Smoke (SHS). OMB approval is being requested for two years.

Secondhand smoke (SHS) is defined as exposure to tobacco smoke by nonsmokers. SHS contains more than 4,000 chemicals of which at least 250 are harmful and more than 50 are carcinogenic (1). The Surgeon General’s summary of literature on smoking has concluded that there is no safe level of exposure to SHS; even brief exposure can harm health (2). The health risks associated with cigarette smoking and exposure to SHS are well established and recognized as major contributors to the foremost causes of death in the United States (2). Numerous epidemiological studies have documented the link between secondhand smoke and increased morbidity and mortality. The Surgeon General’s report documents that over the past two decades, the scientific, engineering and medical literature have established a wide range of adverse health effects from SHS, including cardiovascular disease, lung, breast and nasal sinus cancer, asthma and other respiratory illnesses, low birth weight, and sudden infant death syndrome in newborns. SHS exposure is estimated to result in $5 billion a year in direct medical costs and an additional $5 billion in indirect costs in the U.S. each year (3, 4).

Smoking in residential settings presents serious and substantive health hazards as well as significant challenges in protecting the health and wellbeing of residents. Individuals who choose to make their own units smoke-free, but reside in close proximity to one another in MUH facilities, are vulnerable to compromised air quality from the routine operation of heating, ventilating and air conditioning systems that can distribute SHS throughout a building. MUH includes public or private buildings, or portions thereof, containing two or more dwelling or other housing units. Approximately 85 million Americans reside in MUH, which comprises nearly 30% of all housing in the U.S. (5).

Over the past 25 years, Federal, state, and local government actions to protect the public from SHS exposure have increased in public areas, but few of these actions have included mandatory restrictions on smoking in personal living spaces. Rather, most regulatory policies (i.e., laws and the regulations that implement them) apply to workplaces, restaurants, bars, playgrounds, doorways and other locations. The efficacy of smoke-free policies in public spaces (workplaces, restaurants, transportation, etc.) resulted in a 70% decrease at the national level in serum cotinine concentrations from 1988 to 2002 (6). Few studies, however, have investigated the broader impact of jurisdiction-wide strategies designed to protect individuals from SHS exposure in MUH complexes, where SHS can enter individual units from shared air spaces, ventilation systems, windows, elevator shafts, hallways, and holes in walls, pipes and electrical outlets. The private sector has begun to institute smoke-free policies in MUH on a voluntary basis through changes in leasing agreements and advertising; however, smoking restrictions in MUH have largely been limited to common areas and spaces, not individual dwelling units. There are no studies that have examined the impact of smoke free policies by comparing SHS exposure and changes in health outcomes before and after local governments adopt regulatory policies that protect residents from the ill effects of exposure to SHS in their housing units.

CDC proposes to conduct a study addressing the gap in scientific evidence about the impact of jurisdiction-wide strategies in protecting individuals from SHS (hereafter known as smoke-free policies), specifically the magnitude of the exposure, how exposures can be measured, and how exposures change when smoke-free policies are implemented in MUH facilities. The study will also examine the experience of facility operators and residents before a policy has been implemented and then again after implementation.

The specific research aims of the proposed study are:

1. To examine the health impact of smoke-free policies to reduce exposure to SHS in MUH complexes through analysis of environmental and biometric data. Information will be collected from residents of MUH facilities in Los Angeles County, California (LA County).
2. To examine the cost-effectiveness of smoke-free policies to reduce SHS exposure in MUH complexes by surveying the owners/operators of MUH facilities in LA County.
3. To examine barriers and facilitators to the implementation of smoke-free policies to reduce SHS exposure in MUH complexes. Information will be collected from respondents in four diverse geographic locations.
   1. Municipalities in LA County, that have adopted or are considering a variety of regulatory policies.
   2. Respondents from Maine, Minnesota and Florida, states that have diverse experiences and legal frameworks related to smoke-free policies in MUH. Maine and Minnesota have up to ten years of experience in implementing smoke-free standards affecting indoor air quality, whereas Florida prevents local communities from enacting ordinances that are more restrictive than applicable state law.

CDC is authorized to collect the information needed for this study by the American Recovery and Reinvestment Act (ARRA), Public Law 111–5 (**Attachment 1A**) and sections 301 (a) and 317 (k) of the Public Health Service Act) (**Attachment 1B**). In response to this law, The Department of Health and Human Services (HHS) developed an initiative-- the Patient Protection and Affordable Care Act (ACA) (**Attachment 1C**) to revamp our healthcare system from primarily treating disease to maximizing health impact through prevention. While the ACA creates a number of special funding streams, in 2010 the ACA created a new Prevention and Public Health Fund, a repository designed to provide capital for national investment in prevention and public health programs designed to expand and sustain the necessary infrastructure to prevent disease, detect it early, and manage conditions before they become severe (**Attachment 1D**). The Centers for Disease Control and Prevention (CDC) is the primary Federal agency for protecting health and promoting quality of life through prevention and control of disease, injury, and disability. CDC is committed to programs that reduce the health and economic consequences of the leading causes of death and disability, thereby ensuring a long, productive, healthy life for all people.

**Privacy Impact Assessment Information**

**Overview of the Information Collection System**

Information will be collected over a two-year period. The proposed study involves data collection in LA County, using a quasi-experimental pretest, posttest design with an intervention and comparison group to study the health, social and cost impact of implementing regulatory MUH policies. Baseline and follow-up implementation surveys will be collected along with biological and environmental data. This will occur in up to 12 communities where local smoke-free MUH laws were adopted by mid- 2012 and in a comparable group of cities where no laws were adopted during the same period. A sample of 500 MUH residents and 130 MUH operators will be selected from intervention cities with regulatory MUH policies and a comparable sample of 500 MUH residents and 130 MUH operators will be selected from control cities without regulatory MUH policies. To be eligible for the study, an individual unit within a MUH complex must (a) be occupied and (b) not allow anyone to smoke in the unit during the data collection period. The initial selection of cities, described below, is subject to change, depending on the individual city’s progress in adopting regulatory smoke-free MUH policies by mid-2012. The size of the samples will not change even if other cities are ultimately selected. At this time, we expect the intervention cities to include Sierra Madre, Lawndale, Culver City, El Monte, Artesia, San Fernando, San Gabriel, Hawthorne, Carson, Huntington Park, South Pasadena, and Compton. The proposed comparison cities may include: Lomita, Lynwood, Monrovia, Montebello, Alhambra, LaPuente, Monterey Park, Inglewood, Gardena, Maywood, El Segundo, and South Gate. Control cities were identified and paired with an intervention city based on comparable characteristics.

The second component of the study will involve focus groups in Maine, Minnesota, and Florida, in localities that have already adopted and broadly implemented smoke-free MUH policies either as a response to local regulations or voluntarily. A sample of 12 MUH operators will be selected from communities in Minnesota, Maine, and Florida. In addition, a total of 120 residents will be selected to participate in short focus groups, with a maximum of four focus groups being conducted in each state. These states have been added to the policy component of this research in order to expand the generalizability of conclusions made regarding adoption and implementation of smoke-free policies in MUH. The primary data sources for the study will be (a) quantitative data obtained from interviews with 12 MUH operators (four operators in the three study locations, using the same questionnaire as LA County); (b) qualitative data from participants from up to 12 focus groups (an expected total of 120 residents); and (c) quantitative data on the same residents from pre-focus group questionnaires. Results from studies in these three geographic areas, along with results from cities in LA County, can more readily be interpreted at a national population level than could results from LA County alone.

**Items of Information to be Collected**

The information collection instruments supporting this two-part study are the MUH Operator Recruitment Telephone Script (see **Attachment 4A** for LA County and **Attachment 5A** for Minnesota, Maine and Florida); the MUH Operator Baseline Survey (**Attachment 6A**) and MUH Operator Post-Intervention Survey (**Attachment 7A**); the MUH Resident Baseline Survey (**Attachment 8A**) and the MUH Resident Post-Intervention Survey (**Attachment 9A**); a Protocol for Saliva Collection (**Attachment 10A**); a Protocol for Air Monitoring in Multi-Unit Housing (**Attachment 11A**); a Resident Focus Group Telephone Screening Interview Script (**Attachment 12A**); a Resident Pre-Focus Group Demographic and Attitudinal Survey (**Attachment 13A**); and Focus Group Guides for MUH Residents (**Attachment 13B** will be used with Process-Oriented focus group discussions, and **Attachment 13C** will be used with outcome-oriented focus group discussions).

The topics to be addressed by the various data collection instruments include:

**MUH Operator Survey** (**LA County, and Minnesota, Maine, Florida,** **Attachments 4A, 5A, 6A, and 7A**): The overall goal of this data collection is to learn more about how apartment managers put smoke-free policies to reduce exposure to SHS into place and what it takes to carry out that policy. The questions ask about:

* Property characteristics;
* Secondhand smoke-related issues experienced in the apartment complex;
* Existing smoking-related policies;
* Rationale for MUH with no current policies;
* Operator’s knowledge, attitudes, beliefs, and intentions regarding smoke-free housing policies;
* Smoke-free housing policy-related costs in the apartment complex; and
* Operator demographics.
* Demographic and attitudinal information about the operators will be collected so that we can characterize respondents on the basis of age, sex, race, socio-economic status, and smoking history.
* We also ask the MUH operators to provide copies of leasing agreements or other policy statements on their smoke-free policies. This is to provide proven examples of instances where these barriers were avoided, removed, or lessened.
* We also include a short visual assessment of the exterior and common areas of the buildings in each complex where operators are surveyed. Specifically, we will assess presence of a designated exterior smoking area, proximity of the smoking area to windows and doors of the buildings, presence of cigarette butts or other smoking debris on the ground outside the entrance to the building, presence of receptacles for cigarette butts at the entry to the unit or in the designated smoking area, exterior and interior signs on smoking policies, smell of tobacco smoke in the hallways and other interior common spaces (e.g., entry foyer), and other housing conditions known to trigger or exacerbate respiratory conditions (such as proximity to highways, deterioration that can allow pests or moisture to enter the building, poor ventilation). This provides an independent verification of the presence of factors that may mask or confound the effects of smoke-free policies to reduce SHS exposure in the apartment complex.

**MUH Resident Survey** (**LA County,** **Attachments 8A and 9A**): The overall goal of this data collection is to understand residents’ experiences and beliefs about smoke-free policies to reduce exposure to SHS and changes in their health after the policies have been implemented. The survey queries residents about:

* Housing characteristics and environment;
* Secondhand smoke exposure;
* Knowledge, attitudes and beliefs about secondhand smoke, housing policy implementation and enforcement issues;
* Smoking status and cessation behaviors among residents;
* Adult smoking-related illnesses;
* Adult respondent characteristics; and a
* Children’s module, which contains a subset of questions about health conditions and exposure to SHS based on the questions included in the adult component of the survey; demographic and attitudinal information about the residents, and visual observations of the living room and kitchen are collected, such as ventilation that permits SHS to move between units or the presence of other housing conditions that could independently trigger asthma episodes, such as presence of mold or pests.

**Indoor Air Quality (IAQ) (LA County, Attachments 11A and 11A-1):** The overall goal of this data collection is to monitor indoor air quality (IAQ) for a seven day period. The IAQ monitoring enables us to collect data on residents’ exposure to particulates smaller than 2.5 micrometers in diameter that are known to be associated with respiratory conditions. Airborne particle monitoring equipment will measure particle levels for seven full days to capture a representative sample. Field Data Collectors will place monitors in the main living area of each unit in the same location at baseline and follow-up. To reduce the burden of the air quality monitoring to the MUH residents, the pump noise of the monitors will be mitigated with muffling material in a plastic receptacle to eliminate annoyance for unit occupants. We estimate that it will take 30 minutes to set up the equipment and train one resident to complete the household diary. Two data sheets are included in the protocol, one for collecting time-diary data (**Attachment 11A-1**) from household occupants and one for Field Data Collectors to use for collecting basic monitoring information on the timing, placement, and setup of equipment (**Attachment 11A**).

**Saliva Cotinine (LA County, Attachment 10A**):

The overall goal of this data collection is to collect saliva cotinine samples which provide an objective measure of SHS exposure in adults and children. By measuring resident cotinine levels at baseline and follow-up of implementation of smoke-free regulatory housing policies in the intervention cities and comparing them to resident cotinine results in the comparison cities, we are better able to determine the impact of policy implementation on SHS exposure. To minimize use of invasive or uncomfortable procedures, swabs will be used to collect the saliva samples. Participants age six and older will be instructed on how to insert the swab under the front of the tongue. A children’s swab, which has been specifically design to prevent choking, will be used for participants between the ages of two and five. Adult participants will be instructed in saliva collection using the children’s swab and will perform the procedure. This activity will be confined to adults and children over the age of two, who are able to comply with the instructions.

**Focus Groups: (Minnesota, Maine, and Florida,** **Attachments 12A, 13A, 13B, and 13C):** The overall goal of this data collection is to identify similar experiences across locales related to policy development and implementation, especially:

* Ways to avoid, remove, or mitigate barriers.
* Strategies that lead to successful adoption and implementation of voluntary and regulatory policies.
* Strategies to scale local successes in adoption and implementation of voluntary or regulatory policies up to the national level.

A short attitudinal and demographic survey for participants is administered before the focus group starts in order to characterize respondents on the basis of age, sex, race, socio-economic status, and smoking history and identify individual-level factors that might inform the responses to focus group questions.

Access to information in identifiable form will be limited to selected members of the study team and no data will be reported at the level where individual responses can be identified. These data are not disclosed to anyone who is not an authorized user, following the procedures outlined in Section A.10-B. Data collection forms will be designed to so that personally identifiable information (name, address, and phone number) can be separated from response data, and an identification number will be assigned to each respondent. Information will be collected by CDC’s data collection contractor: Healthy Housing Solutions, and subcontractors: Westat, and the Los Angeles County Department of Public Health/Tobacco Control and Prevention Program (LACDPH). Only senior members of CDC contractor/subcontractor staff will have access to the information in identifiable form. The study will be conducted according a security plan approved by CDC’s Office of the Chief Information Security Officer. An electronic data file containing personal identifiers and linkage information will be set up and stored in a password-protected computer in a locked room. Only authorized individuals can access this linkage file. After the data have been connected, personal identifiers will be deleted from the analytical database. No more than minimal risk will be posed to the privacy of participants.

**Identification of Website(s) and the Website Content Directed at Children Under 13 Years of Age**

This ICR does not involve web-based data collection methods or refer respondents to websites. There are no websites with content directed at children less than 13 years of age.

**A2. Purpose and Use of the Information Collection**

The information collected in all study sites (LA County, CA, Maine, Minnesota, and Florida) will (1) provide critical information about the conditions that facilitate or limit establishing and implementing evidence based strategies to protect MUH residents from the ill effects of SHS in their housing units (hereafter known as smoke-free policies), and (2) characterize the reductions in SHS exposure associated with different types of policies. The results of this research should significantly contribute to building an evidence-base that supports CDC’s “Winnable Battles” for tobacco control and that can be broadened to the national level. Information collected in this study will be used to:

1. Document and describe how apartment residents comply with established smoke-free policies in their apartment complexes, are exposed to SHS in their units, and whether they experienced changes in self-reported health conditions (respiratory, cardiac) commonly associated with SHS. By measuring LA County resident cotinine levels at baseline and follow-up after implementation of smoke-free housing policies in the intervention cities and comparing them to resident cotinine results in the comparison cities, we are better able to objectively determine reductions in SHS exposure related to regulatory policy implementation. Similarly, by measuring indoor air quality (IAQ) at baseline and follow-up after implementation of smoke-free housing regulatory policies in the intervention cities and comparing the results to the comparison cities, we will be better able to determine the impact of policy implementation (Research Aims 1 and 3).
2. Describe how MUH managers decide to put smoke-free policies to reduce SHS exposure into place and what it takes to carry out that policy. (This applies to whether the policies are voluntarily adopted or implemented on the basis of state or local regulatory actions (Research Aims 2 and 3)).
3. Describe the factors at the level of the MUH management that contribute to successful implementation of policies to reduce SHS exposure, based on the following (Research Aims 2 and 3):
   1. Property characteristics;
   2. Secondhand smoke-related issues experienced in the apartment complex;
   3. Existing smoking-related policies;
   4. Questions for MUH operators with no current policies;
   5. Operator’s knowledge, attitudes, beliefs, and intentions regarding smoke-rree housing policies;
   6. Smoke-free housing policy-related costs in the apartment complex; and
   7. Operator demographics. (Demographic and attitudinal information about the operators will characterize respondents on the basis of age, sex, race, socio-economic status, and smoking history.)
4. Describe residents’ views of their involvement in the process of adopting and enforcing smoke-free MUH policies to reduce SHS exposure at the apartment complex level. We hypothesize that residents’ sense of psychological investment or control of decisions that influence their living environments may influence their compliance with smoke-free MUH policies. This could be a factor that confounds the effect of any smoke-free MUH policy, whether adopted voluntarily by MUH management or instituted as a response to state or local government actions (Research Aims 1, 2, and 3).
5. Illustrate more nuanced descriptions of residents’ experiences with policy implementation to reduce SHS exposure, using aggregated focus group responses (Maine, Minnesota, Florida) to help to identify (Research Aim 3):
6. The most often experienced and most challenging barriers to adopting and implementing voluntary and regulatory smoke-free policies.
7. Provide examples of how barriers can be avoided, removed, or lessened.
8. Document and describe effective, evidence-based strategies for implementing voluntary and regulatory policies.

**Privacy Impact Assessment**

Access to information in identifiable form will be limited to selected members of the study team and no data will be reported at the level where individual responses can be identified. These data are not disclosed to anyone who is not an authorized user. Data collection forms will be designed to so that personally identifiable information (name, address, and phone number) can be separated from the data collection effort, and a serial number (i.e., ID code) will be assigned to the respondent and used as the principal means of record management. Only senior members of CDC contractors’ (i.e., Healthy Housing Solutions, and its subcontractors Westat’ and the Los Angeles County Department of Public Health’s Tobacco Control and Prevention Program (LACDPH)) will have access to the information in identifiable form. The project will be conducted according to an information security plan approved by CDC’s Office of the Information Security Officer. An electronic data file containing personal identifiers and linkage information will be set up and stored in a password-protected computer in a locked room. Only authorized individuals can access this linkage file. After the data have been connected, personal identifiers will be deleted from the analytical database.

**A3. Use of Improved Information Technology and Burden Reduction**

We have explored other existing datasets in LA County to determine whether resident health status data could be obtained without requiring a lengthy resident interview. Data are not available at the level of geographic specificity needed to match the location of the MUH complexes that will be studied.

We also explored the possibility of web-based or telephone surveys and determined they are not feasible for several reasons: 1) many of the residents we intend to survey do not have phone or Internet access; 2) we need to observe housing conditions as well as obtain residents’ self-report; and, 3) we believe that in-person interviews will allow Field Data Collectors to build rapport with respondents and thus improve participation in the second round of surveys nine months later.

**A.4 Efforts to Identify Duplication and Use of Similar Information**

While earlier federal funding through CPPW provided LACDPH with an unprecedented opportunity to expand its smoke-free MUH policy efforts to reduce SHS exposure, funding constraints precluded using this initiative to conduct MUH research on the social, economic, and health impact of the expected policy adoption and implementation. Further, while a recent comprehensive literature search showed that there is excellent MUH policy research being conducted using cross-sectional methods (7, 8, 9,10,11,12), we could not identify a single published article using more rigorous research designs (e.g., quasi-experimental designs using a baseline and follow-up design strategy for an intervention group and a comparison group). In developing the study design, we conducted a literature search protocol that involved four stages, repeated on three separate occasions approximately three months apart. The primary search engine was Pub Med supplemented by Google. The comprehensive literature search was conducted in the following manner:

1. A general search was initiated using broad subject headings, including “secondhand

smoke policy” (yielded approximately 2,500 citations), “tobacco control policy”

(yielded approximately 900 citations, and “multiunit housing” (yielded approximately

15 citations). Over 1,000 individual journal citation titles were examined.

2. Based on relevance of article title, selected abstracts were reviewed (approximately

100).

1. Among reviewed abstracts, approximately forty full-text journal articles were selected for review.
2. Among reviewed full-text journal articles, approximately twenty were selected as excellent content matches. For these articles, the Pub Med “related citations” category was used to identify articles with similar content.
3. The four-stage search protocol was repeated three times at approximately three-month intervals, with successive searches focusing on more recent publications (identified through sorting citation list by publication date).

This extensive literature search showed that rigorous research designs (e.g., quasi-experimental designs) have not been used to study the adoption of evidence based strategies to protect MUH residents from the ill effects of SHS in their housing units, This study will use a baseline and follow-up, quasi-experimental study design, with an intervention and comparison group to evaluate the health and social impacts and the cost-benefit of such policies in the Communities Putting Prevention to Work (CPPW) jurisdiction of LA County, thus providing CDC and HHS with valuable information that can lead to replicable policies and practices for other jurisdictions throughout the nation.

There are no other studies reported in the published literature that have collected data on the pre- and post- adoption of smoke-free housing policies to reduce SHS exposure from the perspective of both operators and residents in the same MUH complex. In order to minimize response burden and to ensure consistency with other established survey efforts, we conducted extensive literatures searches, reviewed the CDC Smoking and Tobacco Use Question Inventory on Tobacco ( <http://apps.nccd.cdc.gov/qit/quickSearch.aspx>), obtained the questionnaires and consulted with the authors of several of the major publications on smoke-free MUH policies (9,10.12) and adapted as many questions as possible from surveys developed by the federal government or state-based surveys such as the Behavioral Risk Factor Surveillance System (BRFSS). To minimize burden and to use questions previously tested with similar populations or housing types, the MUH Operator and MUH Resident questionnaires adapted questions from the sources described in B.4 **and Attachment 3B**, as well as annotated in the surveys submitted as **Attachments 6A and 7A and 8A and 9A**.

In identifying data collection resources for this study, the Contractor, Healthy Housing Solutions (Solutions) collaborated with internal teams from the subcontractors: Westat, and the Los Angeles County Department of Public Health (LACDPH). The LACDPH has substantial experience in conducting tobacco control efforts, focusing on the adoption and implementation of smoke-free comprehensive regulatory policies to reduce SHS exposure since 2006 and more recently via funding through CDC’s Communities Putting Prevention to Work initiative (CPPW). These teams provided expert overview for the selection of, and modification of existing data collection sources to be used in this study. In addition CDC Subject Matter Experts (SME) have provided input to select and modify data collection sources (see A.8). These extensive efforts substantially reduce duplication of data that have been previously collected.

**A.5 Impact on Small Businesses or Other Small Entities**

Small businesses may be part of this project, since we may randomly select owner-operators of MUH with fewer than 10 units, or fewer than 12 employees. The project attempts to minimize that burden by limiting the frequency of data collection to no more than twice in a year-long period and to an estimated total of no more than three hours of response burden per individual. There is no option to use a short form to collect the data. Questions are held to the absolute minimum required for the intended use of the data. Participation in the study is voluntary.

**A.6 Consequences of Collecting the Information Less Frequently**

Without baseline and follow-up implementation cost and health data, CDC will not be able to assess over time the cost effectiveness and cost and health benefits associated with particular evidenced-based strategies (i.e., regulatory versus voluntary policies to protect MUH residents from ill effects of SHS exposure in their units). This analysis will provide vital information to inform decision-making and future resource allocation by assessing the actual costs of carrying out policy- and environmental change-focused strategies in an assortment of many communities and hard to reach, diverse populations. This information is crucial to the overall evaluation of the impact of these MUH policies and essential for future, successful program planning and implementation throughout the nation. There are only two periods of data collection proposed. Reducing the respondent burden below the estimated levels (that is, reducing the frequency of the data collection) would diminish the utility of the study and inhibit the ability of HHS to respond to anticipated requests for cost data associated with this program. There are no legal obstacles to reduce the burden.

**A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This project fully complies with all guidelines of 5 CFR 1320.5. There are no special circumstances required.

**A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

**A**. As required by 5 CFR 1320.8(d), a 60-day notice for public comments on the proposed data collection activities was published in the Federal Register on **March 23, 2012,** (**Volume 77, Number 57, p. 17065-17066).** A copy of the notice is included as **Attachment 2A**. One non-substantive public comment was received and acknowledge (see **Attachment 2B**).

**B.** Healthy Housing Solutions, Westat and LACDPH consulted with MUH Operators and Residents through their pilot of the MUH Operator and Resident Surveys. Healthy Housing Solutions, Westat, and LACDPH consulted with persons inside and outside the study design team during development of the MUH Operator and Resident Surveys, specifically:

**Subject Matter Experts at CDC Consulted for the Study**

|  |  |  |
| --- | --- | --- |
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**A.9 Explanation of Any Payment or Gift to Respondents**

The amount of the proposed incentives to respondents is based on local cost of living, as measured by Poverty in America’s Living Wage Calculator for LA County and the individual target cities in Minnesota, Maine, and Florida, the US Department of Labor’s average annual wage calculations for California, Minnesota, Maine, and Florida, and incentives offered to the participants in other comparable studies (9, 10, 12). Since the data collection strategy for MUH operators and residents involves more time, through face-to-face interviews and tours of the complexes or individual apartments, the incentive is higher than those that could have been provided for a phone interview or in-person interview without a visual assessment of the building or unit. The $75 incentive for operators reflects the fact that operators are being asked to provide more detailed information than that requested by the households (i.e., detailed cost data, copies of policies, and time to accompany Field Data Collectors on their visual assessments of the property). The $75 incentive for households that participate in IAQ monitoring reflects the fact that residents are being asked to participate in instruction on how to complete a daily diary, complete that diary for seven days, and permit the installation of IAQ monitoring equipment in the home for seven days. This effort is greater than that required in the household interview.

LA County Data Collection Incentives (provided at pre-intervention and post-intervention rounds of data collection):

* $75 gift card incentive per MUH operator interview (2x=maximum of $150 per respondent);
* $50.00 per household interview. (If an additional adult is needed to answer questions about the children in the home, that individual will receive a $10.00 gift card incentive.

(2x=Maximum of $100-$120 per household);

* $10.00 for 1 adult cotinine sample and $10.00 for 1 child cotinine sample (2x=maximum of $40.00 per household); and
* $75.00 if the unit is randomly selected to participate in seven days of air quality monitoring (2x=maximum of $150 per household).

Minnesota, Maine, and Florida: Data Collection Incentives are lower due to lower cost of living (average wage rate). Data only collected once (1x).

* $50 gift card incentive per MUH operator; and
* $50 gift card incentive per MUH resident focus group participant.

**A.10 Assurance of Confidentiality Provided to Respondents**

**A. Privacy Act Determination.** This submission has been reviewed by CDC’s Information Collection Review Office, which determined that the Privacy Act applies. The applicable System of Records Notice is 09-20-0136.

**B. Safeguards**. Healthy Housing Solutions, Westat, and LACDPH have adopted the security safeguards for survey data, as detailed below. The data collection plan of this study has been approved by the CDC IRB (**Attachment 14**). Contractors are not subject to a non-disclosure agreement.

**Safeguards for Respondents**

Healthy Housing Solutions, LACDPH, and Westat are firmly committed to the principle that the privacy of individual data obtained through the MUH Resident and Operator Surveys, site observation surveys, salivary cotinine samples, airborne particle monitoring, and focus groups must be protected. This principle holds whether or not any specific guarantee of privacy was given at time of interview (or self-response). When guarantees have been given, they may impose additional requirements that are to be adhered to strictly. This study is also subject to the LACDPH Health Insurance Portability and Accountability Act protection. Study data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Specifically, the following strategies will be implemented to safeguard the privacy of study data during data collection, data storage, and data management processes.

**Safeguards during data collection**:

Data are collected in a format appropriate for the task assignment; some data are collected on paper forms in the field or the office. Project Managers are responsible for maintaining a written protocol for the collection and chain of custody for the data for each task of this study and for managing the data collection process.

Personal identifiers to be collected by this study include respondents’ name, date of birth, address, phone number, and salivary sample. To protect privacy, Field Data Collectors engaged in collecting study data will be required to complete training on the Protection of Human Subjects prior to collecting study data. Field Data Collectors will maintain personal identifiers in a secure manner, as well as all information or opinions collected in the course of interviews, and any information about respondents learned incidentally during field work. Field Data Collectors shall exercise reasonable caution to prevent access by others to study data in their possession.

Project Managers are responsible for ensuring that all staff and contractors adhere to confidentiality agreements specific to the study and the provisions of the U.S. Privacy Act of 1974 with regard to surveys of individuals for the Federal Government.

**Safeguards during data storage and management:**

Westat will keep physical copies of study data containing personal identifiers and signed consent forms in a locked container or a locked room. Reasonable caution will be exercised in limiting access to study data to only authorized individuals who are working on this study.

Coded identification numbers will be assigned to respondents prior to creating an electronic record. Solutions’ and Westat’s Information Technology support will be responsible for determining adequate security measures in consultation with the project director to protect the privacy of personal identifiers. An electronic data file containing personal identifiers and linkage information will be set up and stored in a password-protected computer in a locked room. Only authorized individuals can access this linkage file. After Phase 1 (Baseline) and Phase 2 (Post-Intervention) LA County data have been connected, personal identifiers will be deleted from the analytical database. No more than minimal risk will be posed to the privacy of participants.

**Planned Controls**:

Multiple technical, physical and administrative safeguards will be used to protect the privacy of study data at Westat and after transfer to LACDPH for analysis under supervision of Dr. Mark Weber.

* Data access is restricted only to authorized users on a password and firewall protected computer. Passwords are not observable or recordable, guessable, and will not be shared with others or stored in a readable format. All computers used for this study will use the most updated antivirus and antispyware protection software. No remote access software will be used on these computers. Computer monitor screens are not visible to other people. Screen savers are password protected. Data will be stored on an encrypted hard drive. Removable disks that will be used to store data will be kept in locked drawer or cabinet. Windows file encryption system is being used.
* Data are stored in guarded buildings and offices. Only authorized personnel with photo identification badges and key cards can access the data storage rooms.
* Electronic study data are backed up at regular intervals on a secured hard drive in an offsite host-based system. Computers are maintained in secure areas, with access limited to authorized personnel. User manuals will be created to facilitate data management and analysis. All personnel who will have access to the study data will be trained and made aware of their responsibilities for protecting the data. Access to data is “role-based” and on a “need-to-know” basis. The project manager will be responsible for authorizing access privileges for each user.
* After the project is completed and all deliverables have been provided, all data collection instruments and forms are indexed by file, boxed, and transferred to a secure location either on-site or offsite. If offsite, the location must be managed by a contractor specializing in document storage. Records will be retained at the secure location for up to seven years from the date of the last data collected, unless a different time period is specified in CDC’s contract. For some studies, a research oversight committee or Institutional Review Board may require the personal identifiers to be redacted prior to long-term storage. Seven years after the anniversary date of the end of the project, the Solutions’ Project Manager has the discretion to dispose of the files at any time. If the files are not redacted, the documents are disposed of in a manner that assures privacy is maintained (e.g., files with personal identifiers can be shredded). After the project is complete and all deliverables have been provided and approved by the CDC, the electronic files (including personal identifiers) are retained onsite on magnetic tape or disc with the paper records in a locked filing cabinet in a secure area. A copy of the electronic file is provided to the Project Manager, who must keep the second copy in a secure locked location. All electronic files on the computer network or personal computer are removed. After seven years, the Project Manager has the discretion to destroy all the electronic files at any time. The electronic link between data and personal identifiers shall be destroyed within one year after the conclusion of the study. (Note: The public use dataset is a public record and will not be destroyed.)

**C. Consent.** Consent is obtained from each MUH operator at the first interview and a copy of the signed consent is provided to the respondent before the interview begins. MUH operators may read the consent or have the consent read to them, whichever they prefer (**Attachments 6A-1 and 6A-2**). Consent is obtained at the first interview in LA County from the randomly selected adult resident surveyed (**Attachments 8A-1** ) and the parent or guardian for the children in the household **(Attachment 8A-3**) before the interview begins. The consents can be read by these individuals or read to them in either English or Spanish. A copy of the signed consent is provided to the respondent before the interview begins. If a child aged seven to seventeen is randomly selected to provide a saliva sample, an assent is read to the child, the child assent is obtained and a copy of the signed document is provided to the parent (**Attachment 10A-1**). Surveys are administered in English or Spanish, depending on resident preferences. Consents for adult focus group participants are obtained prior to participants’ completion of the short attitudinal and demographic survey and the focus group itself (**Attachment 13A-1**). All Minnesota, Maine, and Florida surveys and focus groups are conducted in English.

The consent form to be used emphasizes the voluntary nature of participation, the intended use of the data, with whom the information can be shared, and the legal authority for data collection. Throughout the interview, residents are reminded that they do not have to respond to questions that they do not wish to answer.

Signed informed consent forms will be obtained before respondents provide any information to the Field Data Collector. Field Data Collectors will store the signed consent forms and completed MUH surveys in a locked box in the trunk of their locked car when they are conducting interviews and in a secure location in their home until data can be shipped, via Federal Express, back to Westat. During the data collection process, respondents may refuse to answer any questions, provide biological samples, or install the air monitor in their units.

D. **Nature of Participation**. Participation in this study is voluntary.

**A.11 Justification for Sensitive Questions**

The consent form indicates that this project collects information that may be considered sensitive by a portion of respondents, e.g., .smoking behavior, sex, race, age, socio-economic status, and medical conditions. The information is essential for study purposes. Although the information would not be considered highly sensitive, the research team has put adequate privacy safeguards in place.

**A.12 Estimated Annualized Burden Hours and Cost to Respondents**

**A.12.A Estimated Annualized Burden Hours**

OMB approval is requested for two years to provide flexibility in the information collection start and stop dates. The burden table presented below (Exhibit 1) presents annualized figures for all activities.

MUH Operators

On an annualized basis, the MUH Operator Survey will be administered in-person at baseline and post-intervention to 130 MUH operators in LA County and six MUH operators from Minnesota, Maine and Florida. The same survey instrument will be administered, in English, in all geographic locations (see **Attachment 6A,** Smoke-Free Multi-Unit Housing Policy Study: Operator Survey - Baseline). Content of the post-intervention survey (**Attachment 7A,** Smoke-Free Multi-Unit Housing Policy Study: Operator Survey – Post-Intervention) will be the same or closely aligned with the baseline survey, but some questions may be modified based on analysis of baseline survey results. If changes are needed, CDC will use the Change Request mechanism, prior to fielding the post-intervention survey, to request OMB approval of the modified post-intervention instrument. For each survey, the estimated burden per response is 75 minutes. This estimate includes a structured 45-minute question-and-answer period, followed by an operator-supervised facility tour in which the data collection contractor will record observational data.

MUH operators will be recruited for participation in the MUH operator survey through telephone interviews. The estimated burden per response for each recruitment contact is five minutes. Due to differences in the selection process for MUH operators in LA County versus MUH operators in the Minnesota, Maine and Florida study component, the recruitment scripts vary slightly for these groups (see **Attachment 4A**, Telephone Script for Recruitment of MUH Operators in LA County, and **Attachment 5A**, Telephone Script for Recruitment of MUH Operators in MN, ME, and FL). On an annualized basis, we estimate that 173 MUH operators will be screened in LA County to yield the target number of respondents.

MUH Residents in Los Angeles County

The MUH resident survey will be conducted in LA County. A total of 1,000 residents will be recruited for participation in the two-year study. Each resident will complete a baseline survey (see **Attachment 8A**, Resident Survey – Baseline: Core (sections A-F)) and a post-intervention survey (see **Attachment 9A**, Resident Survey – Post-Intervention: Core (sections A-F)). On an annualized basis, this will result in the collection of 500 baseline surveys and 500 post-intervention surveys per year. We estimate that a total of 1,666 recruitment contacts must be conducted (833 per year, on an annualized basis) in order to yield the target number of qualified adult participants (see **Attachment 8A**, Resident Survey – Baseline: Screening Eligibility section, pp. 4-6). The estimated burden per response for the screening process is five minutes. . For both the baseline survey and the post-intervention survey, the estimated burden per response is 45 minutes.

All 1,000 adult MUH resident survey participants will be asked to provide baseline and post-intervention saliva swab specimens for saliva cotinine analysis (see **Attachment 10A**, Protocol for Saliva Collection). One thousand adult saliva swabs will be collected in each year of the two-year study. In the first year, the 1,000 samples will be for baseline analysis and in the second year, the 1,000 samples will be for post-intervention analysis). Participating adult residents will also provide permission for children over the age of two years to participate in the saliva specimen collection. Five hundred (500) child saliva swabs will be collected in each year of the two-year study (the 500 swabs collected in the first year will be for baseline analysis, and the 500 swabs collected in the second year will be for post-intervention analysis). The Protocol for Saliva Collection includes specific directions for obtaining saliva swabs from children in various age groups, who are expected to require varying levels of supervision and assistance with the saliva swabs. The estimated burden per response for each saliva specimen collection is 10 minutes.

Subsets of adult MUH residents will participate in additional data collection activities. A total of 500 MUH residents will provide baseline and post-intervention information about children in the household by completing the Children’s Module supplement to the core MUH resident survey. On an annualized basis, we will collect 250 responses to the baseline Children’s Module survey (see **Attachment 8A)** and 250 responses to the post-intervention Children’s Module survey (see **Attachment 9A)**. The estimated burden per response for the Children’s Module is 15 minutes.

Over two years, a total of 400 adult MUH residents will provide information on residential air quality (annualized total of 200 adult MUH residents per year). Half of the residents will be from intervention sites and half of the residents will be from comparison sites. These respondents will set up the monitoring equipment and complete the Airborne Particle Monitoring Diary over a seven-day period (see **Attachment 11A,** Protocol for Air Monitoring in Multi-Unit Housing). The total estimated burden for equipment assembly, completion of the diary over a one-week period, and equipment disassembly is 90 minutes.

The MUH Resident data collections will be conducted in English or Spanish. For each instrument referenced above (as well as supplementary documents such as recruitment flyers, consent forms, and instructions), the suffix (e) identifies the English language version of the document and the suffix (s) identifies the Spanish language version of the document (e.g., see Attachment 8A(e) or Attachment 8A(s), etc.).

MUH Residents in Minnesota, Maine, and Florida

Information will be collected from 60 MUH residents who participate in one-time focus group discussions. The Resident Focus Group Telephone Screening Interview Script (**Attachment 12A**), will be used in the recruitment process. Each resident who chooses to participate will complete a brief, five-minute survey immediately before to the scheduled focus group discussion (see **Attachment 13A**, Resident Pre-Focus Group Demographic and Attitudinal Survey). Thirty (30) MUH residents will be asked to discuss process-oriented questions (see **Attachment 13B**, MUH Resident Focus Group Guide – Process-Oriented), and 30 different MUH residents will be asked to discuss outcome-oriented questions (see **Attachment 13C**, MUH Resident Focus Group Guide – Outcome-Oriented). Each focus group will last approximately one hour.

**Exhibit 1** summarizes the burden hours for each category of respondent for each data collection activity. The total estimated burden hours are 1,920.

**Exhibit 1. Estimated Annualized Burden to Respondents**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of Respondent | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
| MUH Operators in Los Angeles County | Telephone Script for Recruitment of MUH Operators in LA County | 173 | 1 | 5/60 | 14 |
| MUH Operator Baseline Survey | 130 | 1 | 75/60 | 163 |
| MUH Operator Post-Intervention Survey | 130 | 1 | 75/60 | 163 |
| MUH Operators in Minnesota, Maine and Florida | Telephone Script for Recruitment of MUH Operators in MN, ME, FL | 6 | 1 | 5/60 | 1 |
| MUH Operator Baseline Survey | 6 | 1 | 75/60 | 7 |
| MUH Operator Post-Intervention Survey | 6 | 1 | 75/60 | 7 |
| Adult MUH Residents in Los Angeles County | Resident Survey – Baseline: Screening Eligibility (pp.4-6) | 833 | 1 | 5/60 | 69 |
| Resident Survey – Baseline: Core (Sections A-F) | 500 | 1 | 45/60 | 375 |
| Resident Survey – Baseline: Children’s Module (Section G) | 250 | 1 | 15/60 | 63 |
| Resident Survey – Post Intervention: Core (Sections A-F) | 500 | 1 | 45/60 | 375 |
| Resident Survey – Post Intervention: Children’s Module (Section G) | 250 | 1 | 15/60 | 63 |
| Protocol for Saliva Collection (Adult) | 1,000 | 1 | 10/60 | 167 |
| Airborne Particle Monitoring Diary | 200 | 1 | 90/60 | 300 |
| Child MUH Residents in LA County | Protocol for Saliva Collection (Child) | 500 | 1 | 10/60 | 83 |
| MUH Residents in Minnesota, Maine and Florida | Resident Focus Group Telephone Screening Interview Script | 60 | 1 | 5/60 | 5 |
| Resident Pre-Focus Group Demographic and Attitudinal Survey | 60 | 1 | 5/60 | 5 |
| MUH Resident Focus Group Guide – Process Oriented | 30 | 1 | 1 | 30 |
| MUH Resident Focus Group Guide – Outcome Oriented | 30 | 1 | 1 | 30 |
|  | Total | | | | 1,920 |

**A.12.B Estimated Burden Hours**

We have estimated the average hourly wage for MUH operators using the California average hourly wage for the U.S. Department of Labor, Bureau of Labor Statistics Occupational Category (SOC code 119141): Property, Real Estate, and Community Association Managers. Because MUH residents could theoretically come from any occupational category, we have used the California average weekly wage for 2010, divided by 40 hours a week, to compute the average hourly rate for MUH Residents. The estimated cost to respondents is $50,098 (Exhibit 2).

**Exhibit 2. Estimated Annualized Cost to Respondents**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Type of Respondent | Form Name | Number of Respondents | Number of Responses per Respondent | Total Burden (in hours) | Average Hourly Wage | Total Cost |
| MUH Operators in Los Angeles Countya | Telephone Script for Recruitment of MUH Operators in LA County | 173 | 1 | 14 | $35.58 | $498 |
| MUH Operator Baseline Survey | 130 | 1 | 163 | $35.58 | $5,800 |
| MUH Operator Post-Intervention Survey | 130 | 1 | 163 | $35.58 | $5,800 |
| MUH Operators in Minnesota, Maine and Floridab | Telephone Script for Recruitment of MUH Operators in MN, ME, FL | 6 | 1 | 1 | $35.58 | $36 |
| MUH Operator Baseline Survey | 6 | 1 | 7 | $35.58 | $249 |
| MUH Operator Post-Intervention Survey | 6 | 1 | 7 |  | $249 |
| Adult MUH Residents in Los Angeles Countyc | Resident Survey – Baseline: Screening Eligibility (pp.4-6) | 833 | 1 | 69 | $25.28 | $1,744 |
| Resident Survey – Baseline: Core (Sections A-F) | 500 | 1 | 375 | $25.28 | $9,480 |
| Resident Survey – Baseline: Children’s Module (Section G) | 250 | 1 | 63 | $25.28 | $1,593 |
| Resident Survey – Post Intervention: Core (Sections A-F) | 500 | 1 | 375 | $25.28 | $9,480 |
| Resident Survey – Post Intervention: Children’s Module (Section G) | 250 | 1 | 63 | $25.28 | $1,593 |
| Protocol for Saliva Collection (Adult) | 1,000 | 1 | 167 | $25.28 | $4,222 |
| Airborne Particle Monitoring Diary | 200 | 1 | 300 | $25.28 | $7,584 |
| Child MUH Residents in LA County | Protocol for Saliva Collection (Child) | 500 | 1 | 83 | N/A | 0 |
| MUH Residents in Minnesota, Maine, and Floridad | Resident Fous Group Telephone Screening Interview Script | 60 | 1 | 5 | $25.28 | $126 |
| Resident Pre-Focus Group Demographic and Attitudinal Survey | 60 | 1 | 5 | $25.28 | $126 |
| MUH Resident Focus Group Guide – Process Oriented | 30 | 1 | 30 | $25.28 | 759 |
| MUH Resident Focus Group Guide – Outcome Oriented | 30 | 1 | 30 | $25.28 | 759 |
|  | Total | | | | | $50,098 |

a Average hourly rate for California, US Dept. of Labor, Bureau of Labor Statistics. Occupation: Property, Real Estate, and Community Association Managers (SOC code 119141) May 2011. Source: http://data.bls.gov/oes/datatype.do.

b May reflect an over-estimate of total respondent cost because 12 operators will not come from LA County.

c Represents average annual hourly wage for CA, since this is where the bulk of residents will be interviewed. Average hourly wage determined from US Dept. of Labor, Bureau of Labor Statistics **Table 6.** **Private industry by State, 2010 annual averages: Establishments, employment, and wages, change from 2009** by dividing 2010 California annual weekly wages by 40 hours. Source: <http://www.bls.gov/cew/ew10table6.pdf>.

d May reflect an over-estimate of total respondent cost because the120 residents will not come from LA County.

**A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**

No costs other than those described in A.12 will be incurred by the respondents to complete this data collection.

**A.14 Annualized Cost to the Federal Government**

***Exhibit 3*** presents the two types of costs to the Government that will be incurred: (1) External contracted data collection and analyses and (2) Government personnel. Total External (Contractor) project cost to the federal government for conducting this program evaluation is $3,988,340.00. The annualized cost is $1,994,170. These costs cover combined labor, fringe, indirect, and subcontract handling fees.

**The government costs** include personnel costs for federal staff involved in project oversight and development of this Information Collection Request; these efforts involve approximately 10% of a GS-13 public health analyst, 20% of a GS-13 scientist, and 10% of a GS-14 scientist. The total estimated annualized cost of Federal government employees is $34,286.

The total estimated annualized cost to the Federal government is $2,028,456.

**Exhibit 3. Estimated Annualized Federal Government Cost Distribution**

|  |  |
| --- | --- |
| **Type of Government Cost** | **Annualized Cost** |
| Fully loaded labor hours by Solutions, Westat, and LACDPH staff and contractors include labor, fringe, indirect, and subcontract handling fees. | $1,994,170 |
| Federal Staff (per year): |  |
| * GS-13 public health analyst at 10% FTE | $8,242 |
| * GS-13 scientist at 20% FTE | $16,447 |
| * GS-14 scientist at 5% FTE * GS-14 scientist at 5% FTE | $4,780  $4,780  (Total Federal Govt.=$34,286 |
| Total | $2,028,456 |

**A.15 Explanation for Program Changes or Adjustments**

This is a new information collection request.

**A.16 Plans for Tabulation and Publication and Project Time Schedule**

A flowchart demonstrating the cost study instrument development and data collection process is displayed as **Attachment 3C**. The comprehensive statistical analysis plan for this project is discussed in Section B and a logic model is provided in **Attachment 3D.**

**Data Analysis Planned for Los Angeles County Data**

All data will be entered into a database at Westat, checked for errors, and cleaned. SAS statistical software package, version 9.3 (SAS Institute Inc., Cary, North Carolina); SUDAAN, version 10.0.1 (RTI, Research Triangle Park, NC); and Mplus software package, version 6.11 (Muthén & Muthén, Los Angeles, California) will be used for data analysis. Mplus will be particularly useful as it allows for the modeling of sampling design (i.e., clustering), stratification, and multilevel influences (e.g., city- MUH complex-level characteristics). The statistical significance level will be set at α=0.05 for a two-tailed test.

Prior to selecting appropriate statistical testing methods, the assumptions for each test will be examined. For example, for parametric tests (e.g., two sample t-test, linear regression test), the Kolmogorov-Smirnov Test will be used to determine whether the study sample came from a normally distributed population. The Levene test will be used to examine the assumption of equal variances. Data transformation (e.g., log transformation) may be used for any non-normal data. If the normal distribution assumption is still not met after data transformation, a nonparametric statistic may be used. The comprehensive statistical analysis plan for this study includes the following:

1) Examine the Phase 1 (Baseline or pre-intervention) characteristics of respondents to the resident and operator surveys and selected apartment complexes by intervention condition through univariate, bivariate, and stratified analyses.

2) Estimate the weighted prevalence, incidence, and mean or median of relevant key outcome variables by intervention condition and timing of survey through univariate, bivariate, and stratified analyses.

3) Evaluate the implementation of citywide smoke-free MUH policy*.*

To determine whether the citywide regulatory MUH policy is implemented as planned in each sampled MUH apartment complex in the intervention cities, we will examine smoking policies in sampled MUH apartment complexes in intervention cities at follow-up and compare findings to the requirements of the city law. A new variable indicating the level of implementation may be created and used as index of intervention condition.

4) Examine the independent effect of the implementation of a citywide smoke-free MUH policy on key outcome variables through multilevel multivariate regression models.

The purpose of the cost-benefit analysis is to quantify the following and to answer the specific research questions for this analysis:

1. Do MUH apartment unit operators report incremental smoking-related costs associated with unit turnover (e.g., cleaning, repainting, etc.), other cleaning costs, insurance, fire damage, other repairs and maintenance, and/or administrative and other costs, and can these incremental costs be quantified for a specified time period?

1. Do MUH operators report quantifiable costs associated with implementing a smoke-free MUH policy to protect residents from the ill effects of exposure to SHS in their housing units, including putting up no-smoking signs, notifying tenants of the new policy (letters, notices, phone calls, posters), revising the current lease to include the smoke-free provision, offering staff education, training, and outreach (e.g., educating tenants, dealing with smoking violations), providing cessation information and referrals to tenants who smoke, legal costs related to policy implementation and enforcement, designating a smoking area for tenants on the property (e.g., purchase of ashtrays, receptacles, benches), and other one-time and/or ongoing costs?
2. Do MUH residents report smoking related illnesses that are significantly different depending on the type of MUH complex overall policies (no smoking allowed in indoor common areas, individual apartments, outdoor common areas, and/or individual outdoor balconies, patios, and yards of units)?
3. What are the estimated medical and other cost implications (e.g., missed workdays and school attendance) associated with extent of smoke-free MUH policies to protect residents from the ill effects of SHS in their housing units, based on integrated findings from resident self-reported illnesses, operator-reported policies, other local health care utilization data, and published research on the economic benefits of reducing exposure to SHS?

The MUH Operator Survey will be the primary data source used to estimate operator costs for implementing MUH policies and incremental operator costs associated with not implementing such policies, addressing questions 1 and 2 above. These MUH Operator Survey results will be examined by subcategories for number of units in complex, average monthly rent, number of residents in unit, and other variables that could be confounders for costs related to smoke-free MUH policies. This analysis of operator data will also be compared with other available published research on landlord costs and smoke-free MUH policies, to determine if the findings from this sample are consistent with related research.

The MUH Resident Survey will be the primary data source for resident-reported smoking-related illnesses. These data will be combined with MUH Operator Survey data on the type of MUH policies, in order to identify differences in resident-reported smoking-related illnesses that could be associated with the smoking-related policies at the corresponding MUH property, addressing question 3 above. Statistical analysis will examine whether these results show a significant difference in smoking-related illness prevalence associated with MUH policies to protect residents from the ill effects of exposure to SHS in their housing units, after controlling for potential confounders. This analysis will also be compared with other available published research on the increased risk of smoking related illness associated with SHS exposure, to determine if the findings from this analysis are consistent with related research.

The MUH Resident and Operator Surveys will also provide some data related to health care utilization by residents associated with smoking related policies at the corresponding MUH property, addressing question 4 above. However, the incidence of significant health care utilization costs related to SHS exposure in this sample, over a limited period of time, might be too low to draw direct conclusions from these data. Therefore, the primary data source for estimating medical cost savings, avoided sick days, and other long term benefits is likely to be derived from a review of related literature. To the extent possible, this analysis will also compare associated environmental data in published research with data collected as part of the MUH Resident Survey, including air sampling and saliva cotinine.

This analysis will also examine other data related to costs and benefits of MUH policies to protect residents from the ill effects of exposure to SHS in their housing units, including any data judged appropriate from the Communities Putting Prevention to Work (CPPW) cost study, the CPPW Prevention Impacts Simulation Model (PRISM) findings, available state or local health care utilization data, and data that can be extracted from other CDC Tobacco Program cost-related reporting systems. The CPPW cost study is expected to provide cost associated with implementing evidence based strategies to protect MUH residents from the ill effects of SHS in their housing units. These data will be allocated on a per unit or other basis for comparison with other data collected. The cost-benefit analysis will also consider benefit estimates that might be extrapolated from other publications where possible, including the impact of smoke-free MUH policies on smoker decisions to quit smoking.

**Data Analysis Planned for Minnesota, Maine, and Florida Data**

The MUH resident focus groups will occur in three different state/local regulatory contexts. We will examine the combined focus group data by state to identify common themes in policy development and implementation, as well as to examine more closely the differences between regulatory and voluntary approaches to protecting residents from ill effects of exposure to SHS in their housing units (**Attachments 12A-1 and 12A-2** for resident focus group recruitment materials). Recruitment for focus groups will be based on four primary variables: smoking status, parental status, residing in market rate or subsidized housing, and type of policy that applies to the unit (smoke-free throughout the property v. smoking restricted to specific locations on the property). Focus groups will be heterogeneous based on these four variables, and each group will have participants residing in different MUH complexes (**Attachment 12A for resident telephone screening interview**).

Separate topic guides have been developed for focus groups; there are common questions across the two guides as well as questions that are unique to each. The Process-Oriented MUH Resident Focus Group Guide is provided as **Attachment 13B** and the Outcome-Oriented MUH Resident Focus Group Guide is provided as **Attachment 13C**.). Both groups will obtain general opinions of residential smoke-free policies. Focus groups will be tape-recorded and transcribed with individual participants labeled by ID number. Transcripts and some quantitative variables will be uploaded into NVivo qualitative data analysis software for review and analysis.

Quantitative data from the pre-focus group questionnaires include demographic, health, and community characteristic items (**Attachment 13A**). Quantitative data from the MUH operator surveys include information on property characteristics; SHS-related issues; existing smoking-related policies; knowledge, attitudes, beliefs, and intentions regarding smoke-free housing policies; policy-related costs; and demographics. Quantitative data will be stored and analyzed in an Excel database.

Secondary data collection will include document review from newspapers, policy and legislative records, and conversations with key informants in each regional location. Information from these sources will be used as background for developing policy models and understanding the context for primary data. Contextual data from secondary sources will be especially useful to identify larger systemic barriers that MUH operators and focus group participants were or were not able to overcome as they developed and implemented policies to protect residents from the ill effects of exposure to SHS in their housing units.

Review and analysis of the focus group transcripts will be guided by the principles of framework

analysis. First, two trained coders from the study team will read all focus group transcripts to familiarize themselves with the data and identify preliminary themes.

*A priori* themes will be used as umbrella categories to develop subthemes relating to barriers, examples of ways to overcome barriers, and strategies for adoption or implementation. Data review of the transcripts and quantitative data from the pre-focus group questionnaires and MUH operator surveys will allow the coders to identify possible ways to organize the transcripts for future analysis based on differences between participant groups and individual participants. Possible ways to organize the transcripts include:

1. Region;
2. Type of non-smoking policy:
   1. Voluntary or regulatory; and
   2. Common areas or all areas.
   3. Parent status;
   4. Smoking status;
   5. Housing complex;
   6. Age;
   7. Gender;
   8. Race/Ethnicity;
   9. Process or outcome focus group guide:

a. Operator attitude toward policy; and

b. Participant involvement in policy development.

Other ways to organize the transcripts may be identified during transcript review or during coding (using the *NVivo software*).

After initial document review, preliminary themes will be discussed with the larger research team to determine final themes and agree on a coding template, which will be entered into NVivo. The two coders will then independently analyze one transcript, compare results to assess inter-rater reliability for individual themes, and revise the coding template as necessary. The coders will use the final coding template to code all transcripts (including recoding the first “test” transcript). Coders will draft a “Phase 1 Summary” of common themes with representative quotes and the percentage of participants that mentioned a particular theme. The Phase 1 Summary will be organized using research questions as umbrella themes.

During the next phase of qualitative data analysis, coders will run crosstabs in NVivo using the organization criteria above to create comparison groups. Intergroup differences will be summarized and documented in a “Phase 2 Summary” using descriptive measures such as frequencies. The purpose of the Phase 2 Summary is to highlight differences between participant groups with implications for the research questions, for example, how local characteristics influence policy barriers and examples of how barriers were overcome. Quantitative data from the pre-focus group questionnaires and MUH operator interviews will be used to provide context for results from qualitative analyses. The number of MUH operators completing the interview is not large enough to conduct meaningful statistical analyses; however, these interviews will provide basic information on the policy context in each regional location and may clarify individual participants’ experiences and responses.

**A.16.1 Publication Plan**

This research project will generate two manuscripts for submission to peer review journals related to the LA County data collection. It will also produce a case study on MUH smoke-free policy adoption and implementation in Minnesota, Maine, and Florida that identifies strategies that may be “scaled up” nationally for use in other locations. In addition, we have identified the following strategies to disseminate the study findings and ensure that the study findings will be widely received and correctly interpreted:

1. Engage key stakeholders at the initial stage of the project and incorporate their needs and input into the study planning;
2. Prepare key stakeholders to use the study findings by discussing how potential results and study outcomes might affect their decision-making, exploring positive and negative implications of potential data, and identifying different options for program improvement;
3. Tailor interim and final reports and recommendations to meet the needs of different key stakeholders;
4. Conduct follow-up dialogue with key stakeholders and provide training and technical assistance to ensure that the study findings are properly used, recommendations are correctly understood, and lessons learned are addressed in future public health practice; and,
5. Share study findings and lessons learned with key stakeholders in multiple formats.

**A.16.2 Project Timeline**

The expected time schedule for project activities is presented in ***Exhibit 4***.

**Exhibit 4. Estimated Time Schedule for Project Activities**

|  |  |
| --- | --- |
| **Activity** | **Expected Timeline** |
| Data Collection Activity 1 – Pilot | Completed October 31, 2011 |
| Recruitment of MUH Operators – LA County | 1-2 months after OMB approval, Planned for August – November 2012- |
| Recruitment of MUH Residents – LA County | 1-2 months after OMB approval, Planned for September – November 2012 |
| Recruitment of MUH Operators – MN, ME, & FL | 1-2 months after OMB approval, Planned for August-November 2012 |
| Recruitment of MUH residents for focus groups –MN, ME, & FL | 1-2 months after OMB approval, Planned for August-November 2012 |
| Completion of Phase 1 (Baseline) LA MUH Operator Surveys | November 2012 |
| Completion of Phase 1 (Baseline)LA MUH Resident Surveys | November 2012 |
| Completion of MN, ME, FL MUH Operator surveys | November 2012 |
| Completion of MN, ME, FL MUH Resident Focus Groups | November 2012 |
| Validation of MN, ME, FL MUH operator and focus group data | December 2012 |
| Analysis of MN, ME, FL MUH operator and focus group data | January – March 2013 |
| Completion of Phase 2 (Post-Intervention) LA MUH Operator Surveys | Planned for July 2013 |
| Completion of Phase 2 (Post-Intervention) LA MUH Resident Surveys | Planned for July 2013 |
| Validation of LA survey data | Planned for August-September 2013 |
| Analysis of LA survey data | October – December 2013 |
| Draft manuscripts: 1) case study of MN, ME, and FL policy development and implications: 2) analysis of pre/post quasi-experimental design data for Los Angeles | 1) September 2013; 2) February 2014 |
| Collection of secondary sources of health and cost data for LA to compare to LA MUH Operator and Resident Data additional analyses of costs of implementation | October 2012 – January 2014 |
| Analysis of secondary data and comparison to LA MUH operator and Resident Survey data | February – May 2014 |
| Draft manuscript – cost-benefit analysis for Los Angeles | August 2014. |

**A.17 Reason(s) Display of OMB Expiration Date is Inappropriate**

No request for an exemption from displaying the expiration date for OMB approval is being sought.

**A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

No exceptions to the certification are requested.

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