AIM to Improve Asthma

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Protocol Title: AIM to improve Indoor Air: Airflow Improvements during Meal-prep
Protocol Type: Biomedical Non-Exempt
Date Submitted: 05/30/2022
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* * * Subject Population * * *

5. Subject Population

a) Describe proposed subject population, stating age range, gender, race, ethnicity, language and literacy.

We will recruit study participants in the East Bay area of Northern California, from the cities of Rodeo, Hercules, Tara Hills, Pinole, El Sobrante, San Pablo, Richmond, El Cerrito, Albany, Berkeley, Oakland, and Alameda. This area has a total population over 850,000 people and contains census tracts ranked in the top 10th percentile statewide for highest aggregate socio-demographic and environmental burdens, including several in the top 99th-100th percentile for asthma burden.

The study population will consist of children age 6-12 with and without asthma who live in homes with gas stoves and range hoods that vent to the outdoors. As of 2019, there are approximately 120,000 children ages 5-17 living in these cities. Using 2014 data 10-20% of those children have asthma. We plan to recruit up to 60 families, a very small percentage of the available population.

We anticipate that the study population will reflect the greater area population and therefore be roughly 50% male, 50% female, 32% non-Hispanic White, 19% non-Hispanic Black, 18% non-Hispanic Asian. Roughly 25% will be Hispanic or Latinx. (These estimates use 2019 Census bureau 5 year estimates).

b) State the maximum number of subjects planned for the study. This number should account for all subjects to be recruited, including those who may drop out or be found ineligible. Explain how number of subjects needed to answer the research question was determined.

There will be 120 subjects (60 children and 60 parent's guardians) recruited, as per the power analyses below. If the household has more than one eligible child, only one will be eligible for recruitment. One caregiver in each household will also be recruited/enrolled.

Power for Exposure Analyses. In THE AQUA study the adjusted mean difference in PM2.5 between homes that used the stove hood (ever) and those that never did was 5 mcg/m3 (standard deviation 8.24).[35] Using Cohen's equations for t-tests (assuming alpha= 0.05 and beta=0.2), if we expect to see at least a 7 mcg/m3 difference with an intentional cooking ventilation intervention, we would expect to be able to detect that difference with 23 households in each group. Belanger and colleagues[32] showed that the average NO2 level in suburban American homes was roughly 10 ppm, and homes that use gas stoves have NO2 levels 2-5 times those that do not.[19,57] Thus we estimate that a ventilation intervention in homes with gas cooking could decrease NO2 7 ppb. To detect a different of this size requires 28 families per group; ours will have 30.

Power for Clinical Analyses.An intentional use of kitchen ventilation may decrease the PM2.5 levels by 10 mcg/m3 or more, which could decrease FeNO 7 ppb based on work by Mar et al.[26] The minimum detectable change in FeNO for a group size of 30 is 3.3 ppb. As some of the patients may be on corticosteroids, we also calculated a minimum sample size of those off daily medications; that sample size is 24 children. Stanojevic et al[58] report that the coefficient of variation for FEV1 in late childhood and early adolescence is roughly 10%, suggesting a standard deviation of roughly 10. For 30 per group, the minimum detectable effect size will be 0.296, or a minimum detectable FEV1 difference of 2.9 percent of predicted.

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We might recruit up to 65 child/guardian pairs to allow for dropouts.

c) **If any proposed subjects are children/minors, prisoners, pregnant women, those with physical or cognitive impairments, or others who are considered vulnerable to coercion or undue influence, state rationale for their involvement.**

Inclusion of Women and minorities
All children ages 6 to 12 and their families in our study area will be eligible for the study regardless of gender, race or ethnicity. We anticipate that the study population will reflect the diversity of the area as described in 5a.

Inclusion of Children
As this study aims to evaluate an intervention for the homes of children, it is necessary to include children in the study. The study will recruit children ages 6-12- those younger than age six will be excluded as they are unlikely to be able to cooperate with the breathing test techniques (spirometry and exhaled nitric oxide). Drs. Balmes and Harley have both conducted prior work with children, and as a board-certified pediatrician, Dr. Holm has extensive experience working with children.

6. Recruitment

a) **Explain how, where, when, and by whom prospective subjects will be identified/selected and approached for study participation. If researcher is subject's instructor, physician, or job supervisor, or if vulnerable subject groups will be recruited, explain what precautions will be taken to minimize potential coercion or undue influence to participate. See CPHS Guidelines on Recruitment for more information.**

We will recruit from East bay clinics where children are seen, using contacts previously established by the investigators. The Contra Costa Health System (CCHS) Clinics and UCSF Benioff Children's Physicians-Hilltop Pediatrics Clinic expressed their support (beginning in 2018) to serve as recruitment sites. We will post recruitment fliers in the clinic (see Recruitment Tear off flyer in attachments), and have study information cards that physicians can give to children with asthma (see RecruitmentCards in attachments). Physicians will be clear that whether or not the patient participates in the research project will have no effect on their patient-doctor relationship and that as a research study there may be no direct benefit on the patient's asthma, as included in the script.

Due to the paucity of in-person visits happening at the Contra Costa County Health Clinics and Hilltop (due to COVID), recruitment at those sites was supplemented in the spring of 2021 with a postcard mailing to all patients aged 6-12 with a diagnosis of asthma (see PostcardCCHS and PostcardHilltop in attachments). The postcard design was developed in collaboration with each clinic so as to be something that their clinic is comfortable providing to their patients. We provided the printed postcards, stamps and printable address labels to the clinics and they will identify patients in their system and send the mailings. No patient information will be provided to any other members of the study team. Those at the clinics will access patient PHI solely for purposes of recruitment, which is necessary for the research, and no PHI will be removed, physically or electronically, from the clinics.

As of April 2021, Lifelong-Jenkins clinic, Kiwi pediatrics and UCSF Benioff Children's Hospital Oakland (BCHO) Outpatient clinics are also willing to assist with recruitment. We will post recruitment fliers in the clinics (see Recruitment Tear off flyer in attachments), and we have study information cards (see RecruitmentCards in attachments) that physicians and staff can give to children with asthma. Physicians

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and staff will be clear that whether or not the patient participates in the research project will have no effect on their patient-doctor relationship and that as a research study there may be no direct benefit on the patient's asthma, as included in the script.

We are also going to post recruitment fliers and leave recruitment cards in community spaces where kids and families may spend time (e.g., local library), at other clinics where no staff are participating in any recruitment activities (not handing out cards or otherwise). We will also post a digital version of our recruitment card on the West Contra Costa School District Digital Bulletin Board and at the appropriate newsletter/e-bulletin board for other school districts in our study area. We will provide digital flyers to other community organizations that regularly distribute materials to families, for inclusion in their outreach (newsletters, digital bulletin boards). We have also developed a social media kit (Facebook post, Instagram post and twitter post) that can be used by local community organizations to share information about the study. Drafts of all these are attached and, in all cases, interested people are referred back to our email and phone number. No community organizations will be involved in recruitment or screening in any way.

We have a webpage for the study at https://cerch.berkeley.edu/research-programs/aim-study-airflow-improvements-during-meal-prep. The webpage uses the same language and graphics as our recruitment materials. We have also set up a Facebook page for the study (using the same graphics with the same pre- approved language as the website and recruitment cards), which we will use to post the Facebook post shared above, so that others can share it from our posting. We will not communicate with anyone about the study on Facebook, instead referring them to our phone or email. Study staff will not be provided with access to any private Facebook groups, but rather the appropriate administrator of any Facebook groups will make the posts using the approved recruitment language, on behalf of investigators.

b) Describe any recruitment materials (e.g., letters, flyers, advertisements [note type of media/where posted], scripts for verbal recruitment, etc.) and letter of permission/cooperation from institutions, agencies or organizations where off-site subject recruitment will take place (e.g., another UC campus, clinic, school district). Attach these documents in Attachments section. Please see eProtocol Attachments Check List for Non-Exempt Applications for more information.

Recruitment materials attached include:
1- a flyer with tear off contact information for posting in the lobby of the recruiting clinics
2- recruitment note cards to be handed out by clinicians to the parents of patients with asthma (this text will be the same on versions that have graphics on the reverse- the same graphics as the recruitment postcards)
3- scripts for recruitment (including for clinicians when giving out note cards and for recruitment phone or email contacts)
4- digital recruitment flyers including both letter size versions and social media optimized graphics, as well as accompanying social media text

c) Will anyone who will be recruiting or enrolling human subjects for this research receive compensation for each subject enrolled into this protocol? If yes, please identify the individual(s) and the amount of payment (per subject and total).

No.

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7. Screening

a) Provide criteria for subject inclusion and exclusion. If any inclusion/exclusion criteria are based on gender, race, or ethnicity, explain rationale for restrictions.

We will recruit children ages 6-12. They will be eligible for this study if:
-they live in Rodeo/Hercules/Pinole/Tara Hills/El Sobrante/Richmond/San Pablo/El Cerrito/Albany/ Berkeley/Oakland/Alameda
-they are between 6-12 years old
-they have both a gas stove and a range hood that exhausts to the outdoors.
-they live a majority of the time at one household

They will be excluded from the study for:
-living with a smoker who smokes indoors
-if they know they will not have stable housing for the next 3 months
-not fluent in English

b) If prospective subjects will be screened via tests, interviews, etc., prior to entry into the "main" study, explain how, where, when, and by whom screening will be done. NOTE: If screening data will be used for research purposes beyond determining eligibility, consent must be obtained for screening procedures as well as "main" study procedures. As appropriate, either: 1) create a separate "Screening Consent Form;" or 2) include screening information within the consent form for the main study.

At the time of initial recruiting contact, a brief screening interview will be conducted. Due to the COVID-19 pandemic, all recruitment and screening will occur remotely. Study subjects will call the study after being exposed to our recruitment materials. When a parent/guardian calls our phone number to express interest in the study, study staff will return the phone call and perform the screening interview over the phone, getting a verbal consent for screening first (using the unsigned screening consent form). Screening Data will be recorded so that included and excluded participants can be compared.

The study staff will ask if the child is age 6-12, if they have been diagnosed with asthma by a physician (though they are eligible whether or not they have asthma), if they have any other medical conditions, if they live with any smokers, if they have plans to move in the next few months, whether they are fluent in english, whether they have a gas stove in their home and whether they have a range hood that vents to the outdoors.

8. Compensation and Costs

a)

Describe plan for compensation of subjects. If no compensation will be provided, this should be stated. If subjects will be compensated for their participation, explain in detail about the amount and methods/ terms of payment.

Include any provisions for partial payment if subject withdraws before study is complete.

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When subjects are required to provide Social Security Number in order to be paid, this data must be collected separately from consent documentation. If applicable, describe security measures that will be used to protect subject confidentiality.

If non-monetary compensation (e.g., course credit, services) will be offered, explain how

At the time of each in-person study visit, families will be given a $20 Visa gift card, such that by the end of the three visits they will have received $60 total (in visa gift cards). An additional $40 in gift cards will be given to the families at the final visit if all study equipment has been returned, in working order. Furthermore, after assessment of airflow through the range hood, all hoods with inadequate flow will be replaced (where feasible). Thus, in addition to monetary compensation, families will get either a verification that their range hood is functioning adequately, or a new replacement hood.

b) **Discuss reasoning behind amount/method/terms of compensation, including appropriateness of compensation for the study population and avoiding undue influence to participate.**

$100 is an appropriate amount to compensate the child and their guardian for their time. Given that there is the additional benefit of a replacement hood (or verification that theirs functions with adequate airflow), we feel this compensation balances the risk of coercion with the need to adequately compensate the participants.

c) **Costs to Subjects. If applicable, describe any costs/charges which subjects or their insurance carriers will be expected to pay. (If there are no costs to subjects or their insurers, this should be stated.)**

There will be no cost to the insurers. It is possible that there could be a slight increase in electricity use by the subjects due to the use of our measuring devices or increased use of their range hood, but this should be no more than a few dollars over the duration of the study. Other than this, there are no costs to the subjects. Subjects are not liable for lost, stolen or damaged equipment.

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* * * Study Procedures, Alternatives to Participation * * *

9. Study Procedures

a) **Describe in chronological order of events how the research will be conducted, providing information about all study procedures (e.g., all interventions/interactions with subjects, data collection procedures etc.), including follow-up procedures. If any interviews, questionnaires, surveys, or focus groups will be conducted for the study, explain and attach one copy each of all study instruments (standard and/or non-standard) in the Attachments section. Please see eProtocol Attachments Check List for Non-Exempt Applications for more information. If the proposed research involves use of existing data/specimens, describe how data/specimens will be acquired.**

Recruitment and Screening will occur as described in sections 6-7.
This will be a pilot before-after trial, with all participants receiving an educational intervention (and range hood replacement if necessary) after approximately two weeks of baseline data collection, to be followed by approximately two weeks of data collection after the intervention.

Note that all home visits will be performed by adult study staff (not high school youth researchers). The high school students will be engaged in ancillary tasks related to the study which do not involve home visits.

INITIAL CONSENTING and BASELINE DATA PHONE VISIT

Prior to the home visit, parental permission and child assent will be obtained via phone. Using the parent's preferred contact method (email or text), they will be sent unique links to complete their consent forms. Study staff will go over the consents with them via phone. Following the consenting process, parents will be offered the option of completing the rest of the baseline data phone visit at that time, or scheduling another time to complete it. Consents and all data will be recorded into REDCap.

The guardian will also be asked whether they are the owner of the dwelling in which they live, and if so, they will be asked to sign an agreement confirming that they allow a licensed contractor, hired by the study team to perform measurements and to replace the range hood if the current range hood does not meet the performance targets. The performance targets are: the installed range hood or over the range microwave must not produce sound level louder than 60 dbA when exhausting air at 100 cubic feet per minute (cfm) or higher. The requirement of 100 cfm of airflow was selected as it is the minimum requirement of the current California Building Code (as of November 2020).

If the guardian is not the owner of their dwelling, they will be provided an agreement that they can provide to the owner/responsible party of the dwelling. The guardian will subsequently need to provide back to the study team this agreement prior to the continuation of study activities, signed by the dwelling owner for the study team this agreement prior to the continuation of study activities, signed by the dwelling owner for the assessment and possible replacement of the stove hood.

Those agreements-approved by UCB legal, UCOP legal and UCB risk management- are attached in section 22. In addition to the agreements, there is a one-page informational sheet (also in attachments) about the work to be done on the range hood as part of the study (also approved by UCB legal) that can be provided by the participant to their landlord.

At the baseline data phone visit, study staff will conduct interviews to complete the baseline

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At the baseline data phone visit, study staff will conduct interviews to complete the baseline questionnaires: the modified ISAAC Core Questionnaire (a four-page questionnaire about asthma and associated diseases), the ISAAC Environmental Questionnaire (a one-page excerpt of a questionnaire regarding environmental exposures at home) and the baseline cooking survey (a two-page Questionnaire about cooking behaviors in the household and some demographic information about the parent). Portions of the ISAAC Core questionnaire assess general medical history (whether a child has ever had symptoms consistent with asthma, allergies or eczema), these questions will be asked of all children. The questions specific to an asthma diagnosis will only be asked of the children with asthma.

HOME VISIT #1:
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2 days prior to the home visit an appointment reminder will be sent, with a link to complete the visit surveys to complete via REDCap: the childhood Asthma Control Test (cACT, only if the child has asthma, a one-page symptom questionnaire) and the follow up cooking survey. These surveys should take no more than 5-10 minutes.

This visit will occur at the participant homes. An assessment of the cooking ventilation present in all participant's homes will be performed at the time of the first study visit. This will include verifying that a range hood is present and exhausting to the outdoors. If a hood is present, functional and exhausting to the outdoors, a measurement of the airflow through that hood will be performed by an experienced range hood assessor who is also a licensed contractor. If air flow is less than 100 cfm or noise levels are intolerable (>60 dBA) for settings >100 cfm, the range hood will be replaced with a functioning range hood model during or prior to visit #2. The range hood assessment will be performed in approximately 30 minutes to minimize the duration of this first visit. At the time of this measurement, the contractor will also assess how much work is necessary to replace the range hood in this dwelling and whether it is feasible within the study timeframe and budget.

All other procedures will be performed by a study staff member attending the visit, concurrent with the range hood assessment to avoid prolonging the visits. A Digisense Data Logging Vane Anemometer will be affixed to the existing range hood. This will collect and log real-time air flow data to monitor the frequency of ventilation use prior to the educational intervention. Following the intervention, anemometers will be transferred to the new devices if installed. Real-time stove use data will also be collected using lascar easylog thermocouple data loggers and Hobo temperature loggers, which use temperature data to derive cooking intervals, also installed by the study staff member. The temperature loggers have a small box with the batteries and memory, a protected wire and a thermocouple. The thermocouple will be fixed in place on the stove with either magnets or a small amount of heat-resistant tape.

PM2.5 and NO2 levels will be measured in the primary living area of each home. The primary living area of the home is chosen as a location which can well-represent the exposure received by the occupants. Home PM2.5 levels will be measured and logged every 1 minute in each household using an eLichens real-time PM2.5 and NO2 sensor (which transmits data securely to the cloud). If necessary (eg. in the case of equipment failure), we may substitute the eLichens with a similar low-cost sensor such as the IQAir or clarity sensors. The air pollutant sensors will be positioned in the participant homes by the second staff member during this home visit. The sensors are approximately 6.5x3.5x3.5 inches, and will simply be placed on an available surface of furniture (coffee table, bookcase etc). A second small NO2 sensor (an Ogawa passive sampler) will also be placed with the eLichens real-time sensor. The Ogawa is a small cylindrical passive sampler (2 inches x 1 inches), which simply collects NO2 on a filter medium for the duration of the deployment. Ogawa samplers will be set next to the eLichens during this visit and a zipper seal plastic bag will be left with the participant. During the home visit, photographs will be taken of the heater, range hood, stove and measurement devices once they have been set up in the participant homes

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to document the placement.

The child (regardless of asthma status) will perform two breathing tests (spirometry and fractional exhaled Nitric Oxide (FeNO)) with assistance from study staff. The child will perform fractional exhaled Nitric Oxide testing first, using the Niox VERO device. For this maneuver, the child takes a deep breath, puts their mouth onto a similar mouthpiece and exhales slowly and steadily. Spirometry involves breathing through a tube (roughly the diameter of a snorkel) with an attached sensor. We will be using the EasyOne Air Portable Spirometer. First the child takes multiple normal breaths, then a maximal inhalation, followed by a rapid and complete exhalation and ending with a breath back in. The child will not be inhaling any medications as part of our study. During this visit it is possible that photographs will be taken of the breathing tests that include study participants and their parent/guardian, if the parent/guardian has consented to this.

At the conclusion of the lung function testing, the child and their guardian will again have an opportunity to ask any questions of the staff. At the completion of the home visit, the family will be provided $20 in compensation for their time.

CONTRACTOR

If the airflow through the stove hood was deemed inadequate at visit one, this will be replaced by a licensed general contractor (either at home visit 2 or in the period between the home visits 1 and 2), wearing appropriate PPE. The subjects will not be responsible for any expenses associated with installing the range hood, and the general contractor will not have access to any study data other than those data that they access in their usual scope of work (building addresses, building owner contact information, the stove range hood measurements that they perform). If the contractor notes the presence of unsafe conditions that they are unable to remedy (e.g., faulty electrical wiring) or features that would exceed the study budget, stove hood installation will not proceed and participants will be released from the study population. In that case the range hood will be left in, or returned to, the condition it was in at the beginning of the study.

HOME VISIT #2: (approximately 2 weeks after the first home visit)
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2 days prior to the visit an appointment reminder will be sent, with links to complete the surveys to complete via REDCap (cACT if the child has asthma and the cooking survey for everyone).
This home visit will be performed by one or two study staff members. Upon arrival, the child and their guardian will be asked to complete their surveys on a tablet if they have not already done so.

The child and their guardian will receive the educational intervention. This intervention will be a short video presentation, which the child and their guardian will watch at that time. They will then be provided the link for them to watch the video again at their leisure. Staff will be available to answer any questions they have about the video.

The educational intervention will consist of a video instructing the child and their guardian on cooking practices to decrease pollution exposure. The youth council has provided crucial feedback during development of the video. Their involvement will help to ensure that the information is presented in a way that will resonate with the local community and will also provide the youth with exposure to developing health education tools. The family will also receive a printed copy of the accompanying infographic as a reminder of the material in the video. The infographic is in attachments, as is a series of 4 screenshots from the video to give a flavor of the animation. The entire video has been provided to Emily Harden-Antonio for review.

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The video features a woman of color who is the cook in her own home, me (Dr. Stephanie Holm), and a diverse group of children at a playground. The video explains that: cooking creates air pollution (even though you can't always see it), that pollutant levels from cooking can reach the same levels achieved by wildfire smoke, that you can decrease pollution by doing 3 things (1) running the range hood every time you cook, (2) cooking on the furthest back burner and (3) moving other cooking appliances closer to the range hood.

The study staff will verify the location and working status of all equipment placed in the home during the prior visit, both with visual assessments and by documenting with photographs. They will collect the ogawa sampler and place a new sampler in its location. The two breathing tests performed in home visit 1 will be repeated during this visit.

At the conclusion of the lung function testing, the child and their guardian will again have an opportunity to ask any questions of the staff and will be given the $20 to compensate them for their time.

HOME VISIT #3: (approximately 2 weeks after the second home visit)
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2 days prior to the visit an appointment reminder will be sent, with links to complete the surveys to complete via REDCap (cACT if the child has asthma and the cooking survey for everyone). There will be an additional 'End of study survey' administered at this visit only.

This home visit will be performed by one or two study staff members, and have all the same components as visit 2, with 2 exceptions. No new ogawa sampler will be left at the end of this study. All study equipment that was placed during visit 1 will now be collected.

At the conclusion of the lung function testing, the child and their guardian will again have an opportunity to ask any questions of the staff and will be given the $20 for participating in the visit, and an additional $40 if all study equipment was able to be collected (up to $60 total).

Note regarding photographs:
Investigators will try their best to take pictures in which the subjects or their belongings cannot be identified, e.g., from the back or not including any faces. This applies to all photographs, including photos of measurement devices as well as photos of children taking breathing tests.

TEXT OR EMAIL REMINDERS
Appointment confirmations will be sent to the family via their preferred method (text/email) roughly 48 hours prior to their appointments.

Once per week families will also receive a text reminder to continue keeping study equipment in place, with or without the reminder about cooking ventilation, depending on whether they've received the intervention yet or not.

RETURN of CLINICALLY RELEVANT INFORMATION
At the conclusion of the lung function testing (spirometry and FeNO) at each visit parents will be offered the opportunity to receive their child's spirometry and FeNO testing results. The most relevant indices can be written down for them, if they choose (see results return template), or the results can be emailed to the parent if that is their preference.

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b) **Explain who will conduct the procedures, where and when they will take place. Indicate frequency and duration of visits/sessions, as well as total time commitment for the study.**

Initial consenting and baseline phone visits will be performed by study staff (either senior staff such as Dr. Holm, or student research assistants, not youth researchers). The initial visit at participant homes will be done by the licensed general contractor and up to two study staff members (not youth researchers). All study staff will be masked at all times.

There will be 3 study visits total over a roughly four-week period, with total visit time of less than 3 hours. The initial baseline phone visit will take approximately 40 minutes. The Home visit is expected to take approximately 40 minutes. Home Visit 2 will take 30-40 minutes and the third home visit will be 30-40 minutes. (All visits will be roughly 10 minutes shorter if families complete their surveys prior to the visit.) Families will get bi-weekly reminders (email or text depending on the parents' preference), to ensure that equipment remains in place and, after the intervention, to remind the families to use their hoods.

c) **Identify any research procedures that are experimental/investigational. Experimental or investigational procedures are treatments or interventions that do not conform to commonly accepted clinical or research practice as may occur in medical, psychological, or educational settings. Note: if the study only involves standard research or clinical procedures, state "N/A."**

The educational intervention (teaching families about the importance of cooking ventilation) will be experimental, but all other procedures are part of standard care.

d) **If a placebo will be used, provide rationale and explain why active control is not appropriate.**

NA

e) **If any type of deception or incomplete disclosure will be used, explain what it will entail, why it is justified, and what the plans are to debrief subjects. See CPHS Guidelines on Deception and Incomplete Disclosure for more information. Any debriefing materials should be included in the Attachments section.**

NA

f) **State if audio or video recording will occur and for what purpose (e.g. transcription, coding facial expressions).**

NA

10. Alternatives to Participation

Describe appropriate alternative resources, procedures, courses of treatment, if any, that are available to prospective subjects. If there are no appropriate alternatives to study participation, this should be stated. If the study does not involve treatment/intervention, enter "N/A" here.

Participants could choose to increase ventilation during cooking on their own (either via stove hood or use of other ventilation sources). They could also use commercially available devices for measuring air

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pollutant levels in their homes.
