PROTOCOL TITLE: Wood stove interventions and child respiratory infections in rural communities

ClinicalTrials.gov Number: NCT02240134

PRINCIPAL INVESTIGATOR(S): Curtis W. Noonan and Tony J. Ward, School of Public and Community Health Sciences, University of Montana, 406-243-4957, curtis.noonan@umontana.edu

RESEARCH LOCATION(S): University of Montana, Missoula, MT; University of New Mexico, Albuquerque, NM; University of Alaska, Fairbanks, AK

DOCUMENT DATE: November 11, 2015

PROTOCOL AND REVISION HISTORY:

Version Approval Date, mm/dd/yyyy	Summary of Change
12/23/2013	Original protocol
08/26/2014	Amendment for approval of recruitment flyers and media
09/22/2014	The following changes were made in the parental permission form 1. We will collect data about your home and child during two, six-month winter periods. For the data about your home, we will conduct up to two visits in the first winter. 2. At each of these visits we will place devices in your home for up to 6 days to measure temperature and dust.
10/27/2014	Data collection protocols and forms
12/23/2014	Addition of wipe sample collection to assess nicotine in homes. Parental permission form revised to include: “Once per winter, we will collect a nicotine wipe sample from a surface in the home that is very rarely cleaned (e.g., top of a door jam).”
05/21/2015	Amendment for approval of recruitment materials
06/22/2015	Amendment for approval of social media and radio recruitment messages
09/14/2015	Amendment to add two question added to Child Symptom Questionnaire: Did anyone in the home miss work because of your child’s illness? No Yes If yes, for how many days:
10/02/2015	Amendment to add two questions to Home Characteristics Questionnaire: Does anyone in the household smoke? No Yes If yes, do they smoke inside the home? No Yes
11/11/2015	Amendment to add End of Winter Home Questionnaires and Knowledge, Attitudes, Behaviors (KAB) survey

ATTACHMENTS:

Original protocol: ‘LRTIR01protocol.12_23_2013’

Data collection protocols and forms: ‘Child Health Measures Visit Protocol 10272014’

End of Winter Home Questionnaires and KAB survey: ‘End of Winter Questionnaires and KAB 11112015’

Statistical Analysis Plan

Form RA-108
(Rev. 11/13)

THE UNIVERSITY OF MONTANA-MISSOULA

Institutional Review Board (IRB)
for the Protection of Human Subjects in Research
CHECKLIST / APPLICATION

IRB Protocol No.: _____

At the University of Montana (UM), the Institutional Review Board (IRB) is the institutional review body responsible for oversight of all research activities involving human subjects outlined in the U.S. Department of Health and Human Services' Office of Human Research Protection and the National Institutes of Health, Inclusion of Children Policy Implementation.

Instructions: A separate application form must be submitted for each project. IRB proposals are approved for no longer than one year and must be continued annually (unless Exempt). Faculty and students may email the completed form as a Word document to IRB@umontana.edu. or submit a hardcopy to the Office of the Vice President for Research & Creative Scholarship, University Hall 116. Student applications must be accompanied by email authorization by the supervising faculty member or a signed hard copy. *All fields must be completed. If an item does not apply to this project, write in: n/a.* Questions? Call 243-6672.

1. Administrative Information

Project Title: Wood stove interventions and child respiratory infections in rural communities	
Principal Investigator: Curtis Noonan and Tony Ward	UM Position: Assoc Professor
Department: CEHS/BMED	Office location: Skaggs
Work Phone: 406-243-4957	Cell Phone:

2. Human Subjects Protection Training

(All researchers, including faculty supervisors for student projects, must have completed a self-study course on protection of human research subjects ***within the last three years*** *(http://www.umt.edu/research/complianceinfo/IRB/) and be able to supply the "Certificate(s) of Completion" upon request. If you need to add rows for more people, contact the IRB office for assistance.*

All Research Team Members (list yourself first)	**PI**	**CO-PI**	**Faculty Supervisor**	**Research Assistant**	**DATE COMPLETED Human Subjects Protection Course**
Name: Curtis Noonan Email: curtis.noonan@umontana.edu	☒	☐	☐	☐	9/20/2011
Name: Tony Ward Email: tony.ward@umontana.edu	☐	☒	☐	☐	12/28/2012
Name: Erin Semmens Email: erin.semmens@umontana.edu	☐	☐	☐	☒	3/26/2013
Name: Desirae Ware Email: desirae.ware@umontana.edu	☐	☐	☐	☒	11/4/2013

3. Project Funding

(If federally funded, you must submit a copy of the abstract or Statement of Work.)

Is grant application currently under review at a grant funding agency? ☒Yes *(If yes, cite sponsor on ICF if applicable)* ☐No		Has grant proposal received approval and funding? ☐Yes *(If yes, cite sponsor on ICF if applicable)* ☒No		
Agency	Grant No.	Start Date	End Date	PI on grant
NIEHS				Ward and Noonan

For UM-IRB Use Only

IRB Determination:

_____ Not Human Subjects Research
_____ Approved by Exempt Review, Category # _____ *(see memo)*
_____ Approved by Expedited Review, Category #_____ *(see* **Note to PI***)*
_____ Full IRB Determination
  _____ Approved *(see* **Note to PI***)*
  _____ Conditional Approval *(see memo)* - IRB Chair Signature/Date: _____
    _____ Conditions Met *(see* **Note to PI***)*
  _____ Resubmit Proposal *(see memo)*
  _____ Disapproved *(see memo)*

Risk Level: _____

Note to PI: Non-exempt studies are approved for one year only. Use any attached IRB-approved forms (signed/dated) as "masters" when preparing copies. If continuing beyond the expiration date, a continuation report must be submitted. Notify the IRB if any significant changes or unanticipated events occur. When the study is completed, a closure report must be submitted. Failure to follow these directions constitutes non-compliance with UM policy.

Final Approval by IRB Chair/Manager: _____ Date: _____ Expires: _____

<In an effort to be environmentally responsible, please expand/reduce box size as needed.>

4. Purpose of the Research Project: Briefly summarize the overall intent of the study. Your target audience is a non-researcher. Include in your description a statement of the objectives and the potential benefit to the study subjects and/or the advancement of your field. **Generally included are literature related to the problem, hypotheses, and discussion of the problem's importance.** Expand box as needed.

Acute lower respiratory tract infections (LRTIs) account for more than 27% of all hospitalizations among US children under five years of age, with recurrent LRTIs in children a recognized risk factor for asthma. Within rural areas of Montana, Alaska, and the Navajo Reservation, research has shown that residential biomass combustion leads to elevated indoor levels of fine particulate matter (PM2.5) that often exceed current healthbased air quality standards. Parallel findings have been observed in several developing countries where biomass combustion is commonly used for cooking and/or heating. This is concerning, as PM2.5 exposure is associated with many adverse health outcomes, including a greater than three-fold increased risk of LRTIs. Currently, there is a global effort to reduce indoor biomass smoke exposures in developing countries through the introduction of improved cookstove technology. Similar evidence-based efforts are warranted in rural and Native American communities in the US that suffer from elevated rates of childhood LRTI and commonly use wood for residential heating. To date, exposure reduction strategies in wood stove homes have been either inconsistently effective or include factors that limit widespread dissemination and continued compliance in rural and economically disadvantaged populations. In this project, we propose to test the efficacy of two intervention strategies for reducing indoor wood smoke PM2.5 exposures and children's risk of LRTI in three unique and underserved settings: (1) rural mountain valley communities in western Montana; (2) Navajo Nation communities; and (3) Alaska Native Villages. We will conduct a three-arm randomized placebo-controlled postonly intervention trial in wood stove homes with children less than five years old. Education on best-burn practices and training on the use of simple instruments (i.e., stove thermometers and wood moisture meters) will be introduced as one intervention arm (Tx1). This intervention will be evaluated against an indoor air filtration unit arm (Tx2), as well as a placebo arm (Tx3, sham air filters). The primary outcome will be LRTI incidence among children under five years of age. To allow for detection of exposure and outcome differences within each of the three regions, a sample of 324 homes, or 108 within each study area will be equally assigned to each of the three intervention arms. The overall hypothesis is that a low-cost, educational intervention targeting indoor wood smoke PM2.5 exposures will be sustainable, and can reduce children's risk of LRTI in underserved Native and rural communities.

This checklist submitted to the University of Montana IRB is specific for the activities in study area 1: rural mountain valley communities in western Montana. As indicated below (item #5) the other two study sites will fall under the jurisdication of the respective local IRBs.

4.1 What do you plan to do with the results? If not discussed above, include considerations such as whether this is a class project, a project to improve a program/school system, and/or if the results will be generalized to a larger population, contribute to the general field of knowledge, and/or be published/presented in any capacity.

Results will be generalized to other communities and households that burn biomass for residential heating. Results of this research will be published in peer reviewer journals.

Is this part of a thesis or dissertation? ☒No ☐Yes If yes and other than the PI's, then whose?

5. IRB Oversight

Is oversight required by other IRB(s) [e.g., tribal, hospital, other university] for this project? ☒Yes ☐ No

If yes, please identify IRB(s):

This study will be approved by The University of Montana Institutional Review Board (UM-IRB). Approval for study site 2 will be submitted to the Navajo Nation Human Research Review Board. Approval for study site 3 will be submitted to the Alaska Area Institutional Review Board (AAIRB), and the Yukon Kuskokwim Health Corporation Human Studies Committee.

6. Subject Information:

6.1 Human Subjects *(identify, include age/gender)*:

Eligible subjects will include children less than 5 years of age that live in a household that utilizes a wood stove as the primary heating source in the study region (i.e., rural Montana). We anticipate an equal number of male and female child participants. A total of 108 households from this study area will be recruited for this study. We assume approximately 1.5 children under 5 years old per household (n = 162 total child subject).

6.2 How many subjects will be included in the study? 162

6.3 Are minors included *(under age 18, per Montana law)*? ☒ Yes ☐ No
If yes, specify age range: 0 to 5

6.4 Are members of a physically, psychologically, or socially vulnerable population being specifically targeted?
☐ Yes ☒ No
If yes, please explain why the subjects might be physically, psychologically or socially vulnerable:

6.5 Are there other special considerations regarding this population? ☐ Yes ☒ No
If yes, please explain:

6.6 Do subjects reside in a foreign country? ☐ Yes *Specify country:* _____ ☒ No
If yes, please fill out and attach Form RA-112, Foreign Site Study Appendix (http://www.umt.edu/research/complianceinfo/IRB/Docs/foreign.doc).

6.7 How are subjects selected or recruited? Include a bulleted list of inclusion/exclusion criteria. ***(Attach copies of all flyers, advertisements, etc,. that will be used in the recruitment process as these require UM-IRB approval)***

For the western Montana study area, we will recruit participants through the local medical center, pediatricians' offices, and the Women, Infants and Children (WIC) programs. In addition, we will communicate directly with obstetricians, pediatricians, and WIC community nurses to describe the study, and provide recruitment materials such as flyers and post cards to be returned by potentially eligible participants.

Inclusion criteria:
- Eligible homes will be any home that uses a wood stove as a primary heating source, and has one or more children under the age of five years. The home must include a parent who is capable and willing to record symptom data for the enrolled children and wood stove usage data.

Exclusion criteria:
- None.

6.8 How will subjects be identified in your personal notes, work papers, or publications: *(may check more than one)*

☐ Identified by name and/or address or other
(Secure written [e.g., ICF] or verbal permission to identify; if risk exists, create a confidentiality plan.)

☒ Confidentiality Plan
(Identity of subjects linked to research, but not specific data [e.g., individuals identified in ICF but not included in publications]; identification key kept separate from data; or, data collected by third party [e.g., Select Survey, SurveyMonkey, etc.] and identifiers not received with data.)

☐ Never know participant's identity
(An ICF may be unnecessary [e.g, anonymous survey, paper or online] ***unless*** *project is sensitive or involves a vulnerable population.)*

6.9 Describe the means by which the human subject's personal privacy is to be protected, and the confidentiality of information maintained. If you are using a Confidentiality Plan (as checked above), include in your description a plan for the destruction of materials that could allow identification of individual subjects or the justification for preserving identifiers.

All households, and child subjects within household, will be assigned unique identification numbers. For practical purposes, the PI or appropriate study personnel will have a linkage file on-site (e.g., a file that identifies the subjects and their corresponding numbers) during the data collection days to ensure that the correct subjects are identified. At all other times, this linkage file will be under the control of the University of Montana PIs. The linkage file will be kept separate from other data materials. When sample collection is completed, this linkage file will be returned to a locked file cabinet under the control of Co-PI Noonan. Data will be recorded on data collection sheets that contain only the subject's identification number and no other personal identifiers.

6.9a Will subject(s) receive an explanation of the research – separate from the informed consent form (if applicable) – before and/or after the project? ☐ Yes *(attach copy and explain when given)* ☒ No

7. Information to be Compiled

7.1 Explain where the study will take place *(physical location not geographic). If permission is required to conduct the research at the location or to use any of the facilities, indicate those arrangements and attach copies of written permission:*

The study will take place in the children's homes.

7.2 Will you be working with infectious materials, ionizing radiation, or hazardous materials? Please specify.

N/A

7.3 Subject matter or kind(s) of information to be compiled from/about subjects:

The primary health outcome will be occurrence of LRTI among children, and will be assessed using active surveillance within the home. Identification of LRTI episodes will occur through a three step process: (1) parent reporting of symptoms; (2) Community Coordinator collection of confirmatory and severity data; and (3) physician classification of case status based on data collected by the Community Coordinator, and when available, data collected from a clinic or hospital.

At the onset of the program in each study area, comprehensive health outcomes assessment training of Community Coordinators will be provided by Drs. Paul Smith and Curtis Noonan. Community Coordinators will then train parents in the identification of symptoms consistent with LRTI (cough, difficulty breathing, fast breathing, noisy breathing, nasal discharge, loss of appetite and fever). Parents will be asked to contact their Community Coordinator when such symptoms are present in household children <five years (Step 1). Home visits will occur within 48 hours of parent notification of signs and symptoms of LRTI. At this visit, the Community Coordinator will interview the parent about each study participant's symptoms. The Community Coordinator will then measure temperature, respiratory rate and saturated oxygen, and evaluate the child for presence of chest indrawing (retractions), wheeze and cough (Step 2). Please note that the Community Coordinators are not diagnosing respiratory illness or providing medical care, and parents will be encouraged to seek medical care for treatment of their child's respiratory symptoms, when indicated (see also Protection of Human Subjects section). For any study participant experiencing symptoms, the Community Coordinator will document the presence of symptoms and date of onset with the parent. During the regular communication with the parent and subsequent home visits, the Community Coordinator will continue to track this child's symptoms. The last day of cough and rapid breathing with no recurrence of symptoms during a following 14 day period will be considered the end date for a given episode. Per approaches used internationally, if symptoms recur within a period of less than 14 days, these symptom days will be considered part of the immediately preceding episode rather than a separate episode. Days with cough as the only symptom will not be included as days for the given LRTI episode. The Community Coordinator will also determine if the child was observed by a health care provider, clinic or hospital during this episode. If available, health data from such visits will be collected from the covered entity with the corresponding parent-signed HIPPA forms. Data collected from medical records will include health care provider diagnosis, ausculatory findings, and laboratory/radiological findings.

The Step 1 strategy may be adversely impacted by lack of follow-up by the parent or communication barriers that may vary by community. To address this, the Community Coordinator will engage in active and frequent surveillance of homes (Step 2), interviewing the parent at a minimum of once every two weeks regarding symptoms among study participants. This communication will occur via telephone, email, or a home visit depending upon the community setting and the preferred method of communication. The Community Coordinator will also visit the home at a minimum of once per month to measure respiratory rate and saturated oxygen, regardless of whether or not the parent has reported child symptoms consistent with LRTI. When indicated the Community Coordinator will collect objective measures and prospectively track symptoms according to the Step 1 procedures indicated above.

For primary analysis, the final case determination will be made by pediatric pulmonologist, Paul Smith, D.O (Step 3). The primary case definition will be based on the objective data collected by the Community Coordinator. Children <5 years will be considered to have LRTI if the Community Coordinator documents cough and a respiratory rate ≥40 breaths per minute in children <1 year or ≥30 breaths per minute in children 1 to <5 years. The primary determinants of LRTI status (i.e., respiratory rate and presence of cough) are easily captured by trained Community Coordinators. The respiratory rate thresholds are highly sensitive indicators for presence of LRTI. To improve specificity for LRTI, Dr. Smith will further distinguish between moderate and severe LRTI (i.e., secondary case status determination)

according to the presence of fever, chest indrawing, wheeze and saturated oxygen readings <90% as documented from direct field observation or from clinical records.

Other data collection: We will capture additional data that may be relevant to either risk of LRTI or PM2.5 exposures. Individual-level characteristics to be captured from parents will include child's vaccination history, occurrence and duration of breastfeeding, birth weight, and maternal age. Household-level characteristics will include crowding, presence of mold, cleanliness, parent education level, household income, and household tobacco smokers. To supplement the reporting of household tobacco use, we will collect household surface dust wipe samples at each exposure sampling visit to measure deposited nicotine. Alcohol wipes will be collected from horizontal surface areas within the home in areas that are not frequently cleaned (top of doors, top of cabinets, etc.). Following a revised method utilized by the US Centers for Disease Control and Prevention,101 analysis for nicotine will be performed from the wipes using Gas Chromatography/Mass Spectrometry (GC/MS) at UM under the direction of Dr. Tony Ward. Exposures could also be impacted at the household level by various factors such as the use of power generators or the use of materials other than wood in stoves, with some activities specific to the study sites.

7.4 Activities the subjects will perform and how the subjects will be used. Describe the instrumentation and procedures to be used and kinds of data or information to be gathered. **Provide enough detail** so the IRB will be able to evaluate the intrusion from the subject's perspective (expand box as needed):

During assessment of suspected LRTI, the Community Coordinator will measure the child's temperature, respiratory rate and saturated oxygen, and evaluate the child for presence of chest indrawing (retractions), wheeze and cough. This will take approximately 15 minutes for each time these factors are assessed for a given child. These same measures will be captured for the child each time the Community Coordinator visits the child's home. These visits will occur once per month for two six-month winter periods, or a total of 12 visits.

7.5 Is information on any of the following included? *(check all that apply)*:

- ☐ Sexual behavior
- ☐ Drug use/abuse
- ☐ Alcohol use/abuse
- ☐ Illegal conduct
- ☐ Information about the subject that, if it became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability.

7.6 Means of obtaining the information *(check all that apply)*. **Attach questionnaire or survey instrument**, if used:

- ☒ Field/Laboratory observation
- ☐ Blood/Tissue/Urine/Feces/Semen/Saliva Sampling *(IBC Application must be submitted)*
- ☒ Medical records *(require HIPAA form)*
- ☒ Measurement of motions/actions
- ☐ Use of standard educational tests, etc.
- ☐ Other means *(specify)*:
- ☐ In-person interviews/survey
- ☐ Telephone interviews/survey
- ☐ On-site survey
- ☐ Mail survey
- ☐ Online survey *(attach Statement of Confidentiality)*
- ☐ Examine public documents, records, data, etc.
- ☐ Examine private documents, records, data, etc.

7.7 Will subjects be *(check all that apply)*:

☐ Videotaped ☐ Audio-taped ☐ Photographed ☒ N/A

(securing an additional signature is recommended on consent/assent/permission forms)

Explain how above media will be used, who will transcribe, and how/when destroyed:

7.8 Discuss the benefits (does not include payment for participation) of the research, if any, to the human subjects and to scientific knowledge *(if the subjects will not benefit from their participation, so state)*:

Those who participate in this research may help inform health researchers, physicians, and the regulatory community about exposure to smoke from wood stoves and the impact of these exposures on susceptible populations. These findings will help identify interventions that will be generalizable to other rural impacted by wood smoke. Information collected from exposure assessments will also be made available to subjects at the end of their participation in the study. These data could be useful for identifying strategies to mitigate in home exposures to PM and respiratory morbidity among children. The study may benefit study participants directly through the collection of objective measures of their respiratory health. Although the Community Coordinators will not be diagnosing children or providing them with medical care, they will have information on normal ranges for respiratory rate, oxygen saturation, temperature and retractions and thus can refer children for medical care or make a recommendation for referral. In these cases, the participants may benefit from receiving care that they might not otherwise have sought.

7.9 Cite any payment for participation (payment is not considered a benefit). If grant funding is not indicated in item #2, please specify the source of the funding and in what form it is to be dispersed.

Households, rather than the child subjects, will be payed for their participation. Each household participating in the project in western Montana will receive $100 per each of two winter periods, or a total of $200.

7.9a Outline, **in detail**, the risks and discomforts, if any, to which the human subjects will be exposed *(Such deleterious effects may be physical, psychological, professional, financial, legal, spiritual, or cultural. As a result, one can never guarantee that there are no risks – use "minimal." Some research involves violations of normal expectations, rather than risks or discomforts; such violations, if any, should be specified)*:

This study will be conducted in the home of children less than 5 years of age. The household intervention does not involve any medications or changes to the child's normal care. The proposed methods for assessing the presence of LRTI are non-invasive, including respiratory rate measures and recording of symptoms.

7.9b Describe, **in detail**, the means taken to minimize each such deleterious effect or violation::

The Coordinators will be trained by our medical consultant to recognize when a child's symptoms indicate the need for medical referral.

8. Informed Consent

An informed consent form (ICF) is usually required, unless subjects remain anonymous or a waiver is otherwise justified below. *(Templates and examples of Informed Consent, Parental Permission, and Child's Assent Forms are available at* http://www.umt.edu/research/complianceinfo/irb/forms.aspx).

- A signed copy of the consent/assent/permission form **must be offered to all subjects**, including parents/guardians of subjects less than 18 years of age (minors).
- Use of minors
    - All minor subjects (under the age of 18) must have written parental or custodial permission (45 CFR 46.116(b)).
    - All minors from 10 to 18 years of age are required to give written assent (45 CFR 46.408(a)).
    - Assent by minor subjects: All minor subjects are to be given a clear and complete picture of the research they are being asked to engage in, together with its attendant risks and benefits, as their developmental status and competence will allow them to understand.
    - Minors less than 10 years of age and all individuals, regardless of age, with delayed cognitive functioning (or with communication skills that make expressive responses unreliable) will be denied involvement in any research that does not provide a benefit/risk advantage.
        - Good faith efforts must be made to assess the actual level of competence of minor subjects where there is doubt.
        - The Minor Assent Form must be written at a level that can be understood by the minor, and/or read to them at an age-appropriate level in order to secure verbal assent.
- Is a written informed consent form being used? ☐ Yes *(attach copy)* ☒ No (*justify below)*
  To waive the requirement for written informed consent (45 CFR 46.117), describe your justification:

- Is a written parental permission form being used? ☒ Yes *(attach copy)* ☐ No
  (If yes, will likely require minor assent form)
- Is a written minor assent form being used? ☒ Yes *(attach copy)* ☐ No
  (If yes, will likely require parental permission form)

Principal Investigator's Statement

By signing below, the Principal Investigator agrees to comply with all requirements of The University of Montana-Missoula IRB, the U.S. Department of Health and Human Services Office of Human Research Protection Guidelines, and NIH Guidelines. The PI agrees to ensure all members of his/her team are familiar with the requirements and risks of this project, and will complete the Human Subject Protection Course available at http://www.umt.edu/research/complianceinfo/irb.

I certify that the statements made in this application are accurate and complete. I also agree to the following:

- I will not begin work on the procedures described in this protocol, including any subject recruitment or data collection, until I receive final notice of approval from the IRB.

- I agree to inform the IRB in writing of any adverse or unanticipated problems using the appropriate form. I further agree not to proceed with the project until the problems have been resolved.
- I will not make any changes to the protocol written herein without first submitting a written **Amendment Request** to the IRB using form RA-110, and I will not undertake such changes until the IRB has reviewed and approved them.
- It is my responsibility to ensure that every person working with the human subjects is appropriately trained.
- All consent forms and recruitment flyers must be approved and date-stamped by the IRB before they can be used. The forms will be provided back to the PI in PDF format with the IRB approval email. Copies must be made from the date-stamped version. All consent forms given to subjects must display the IRB approval date-stamp.
- I understand that it is my responsibility to file a **Continuation Report** before the project expiration date (does not apply to exempt projects). This is not the responsibility of the IRB office. *Tip: Set a reminder on your calendar as soon as you receive the date*. A project that has expired is no longer in compliance with UM or federal policy.
- I understand that I must file a **Closure Report** (RA-109) when the project is completed, abandoned, or otherwise qualifies for closure from continuing IRB review (does not apply to exempt projects).
- I will keep a copy of this protocol (including all consent forms, questionnaires, and recruitment flyers) and all subsequent correspondence with the IRB.
- I understand that failure to comply with UM and federal policy, including failure to promptly respond to IRB requests, constitutes **non-compliance** and may have serious consequences impacting my project and my standing at The University of Montana.

Signature of Principal Investigator: _____ Date: _____
(Type for electronic submission; sign for hard copy)

NOTE: I AM AWARE that electronic submission of this form from my University email account constitutes my signature.

Students and Faculty Advisors: Student applications must be accompanied by either an email authorization from the supervising faculty member or by a signed hard copy (below).

Faculty Supervisor: _____

My signature confirms:

1) I have read the IRB Application and attachments.
2) I agree that it accurately represents the planned research.
3) I will supervise this research project.

Faculty Advisor Signature: _____ Date: _____
(Type for electronic submission; sign for hard copy)

Department: _____ Phone: _____

Child Health Measures Contacts and Visits

Initial visit (at time of recruitment/informed consent):

1. Review parental permission form and answer parent questions.
2. Review and complete HIPAA form.
3. Obtain assent from children age 4 and 5 years of age
4. Upon the receipt of signed parental permission (for all children) and child assent (for children ages 4-5 years), study personnel will ask the contact parent to complete the following documents:
   A. Demographics Form
   B. Home Characteristics Form
   C. Child Birth and Infancy Data
   D. Authorization to Use and Disclose Protected Health Information for Research Purposes

Phone contacts and procedures for parent-reporting of child symptoms:

- Provide study phone numbers.
- Provide instruction sheet for identifying child symptoms (see PARENT/CAREGIVER REPORTING OF SYMPTOMS).
- When parent contacts study personnel, Child Symptom Questionnaire (below) will be completed.

Study personnel also will monitor child symptoms via phone call with contact parent at a frequency of once per two weeks during the winter period. Home visits will supersede phone-based data collection.

In phone communications, the Child Symptom Questionnaire will be completed.

Home visits and data collections:

Home visits will occur at a frequency of once per month during the winter period, or as indicated by phone contact that was initiated either by study personnel or contact parent.

Note: Even if the visit is initiated by illness report for a given child, when another study child resides in the same home, these data also will be collected for that symptom-free child.

At home visit, the following will be collected for each child participant:

- Child Symptom Questionnaire (parent response)
  Note: Even if these symptom data were collected during a phone contact, these symptom data should be collected again at home visit.

- Health Measures Visit Sheet. Protocols for the following are included:
  - Respiratory rate
  - Heart rate and saturated oxygen (i.e., pulse oximetry)
  - Temperature

See also Referral Protocol.

Capture of data from child's health provider visit, when applicable:

If the parent has indicated that the child has been taken to a health care provider (see Child Symptom Questionnaire), study personnel will request data from the respective health care provider. Per the parent-signed "Authorization to Use and Disclose Protected Health Information for Research Purposes," the following data will be requested:

- Diagnosis of respiratory tract infection, including both upper and lower respiratory infection;
- Lab results related to respiratory tract infection
  Any results from respiratory "swabs" if obtained (RSV, influenza, pertussis, parainfluenza)
- presence of fever;
- observation of chest retractions;
- wheeze or other impaired breathing symptoms; and
- saturated oxygen readings
- chest radiographic information (positive or negative findings)

Exposure sampling visits:

During the first winter, up to two sampling visits will occur to collect indoor air quality data. The air sampling equipment will be placed by study personnel and will measure temperature and dust for up to 6 days. The home participants will not need to assist with the air sampling equipment, but we will ask them to complete the following forms:

- Home characteristics
- Home activity Log
- Wood stove usage
- In-home Log

Demographic Questions for Primary Caregiver Home ID:_____

Date: _____

1. Please circle one: Female Male

2. Are you Hispanic or Latino?

   Yes No

3. What is your race? Circle one or more races to indicate what you consider yourself to be:

   American Indian/Alaskan Native

   Asian

   Native Hawaiian or Other Pacific Islander

   Black or African American

   White

   More than one race

4. Circle the category that best describes your household income?

   Less than $20,000

   $20,000 to $29,999

   $30,000 to $39,999

   $40,000 to $49,999

   $50,000 to $74,999

   $75,000 to $99,999

   $100,000 or more

5. Circle the category that best describes your years of school completed:

   Less than high school

   High school diploma or GED

   Some college

   College degree

6. How many total residents are in your home? _____

7. How many children under 5 reside in your home? _____

If you have more than one child under 5 years of age, please answer the following questions starting with the youngest child first:

Questions for Child #1

8. Is your child Hispanic or Latino? Age of Child #1 on November 1st: _____

Yes No

9. What race is your child?

American Indian/Alaskan Native Asian

Native Hawaiian or Other Pacific Islander Black or African American

White More than one race

Questions for Child #2

10. Is your child Hispanic or Latino? Age of Child #2 on November 1st: _____

Yes No

11. What race is your child?

American Indian/Alaskan Native Asian

Native Hawaiian or Other Pacific Islander Black or African American

White More than one race

Questions for Child #3

12. Is your child Hispanic or Latino? Age of Child #3 on November 1st: _____

Yes No

13. What race is your child?

American Indian/Alaskan Native Asian

Native Hawaiian or Other Pacific Islander Black or African American

White More than one race

HOME CHARACTERISTICS DATA SHEET

Technician:_____ Home ID:_____ Winter (1,2,3,etc.):_____

Sampling Dates:_____ Date form completed:_____

To be completed by an adult resident once at the beginning of each winter.

1. Number of total residents in home: _____
2. Number of residents younger than 18 years of age: _____
3. Number of residents younger than 5 years of age: _____
4. Type of home: House Mobile Home Duplex/Apt Other: _____
5. Year home built: _____
6. Square footage of home: _____
7. Number of floors (not incl. bsmnt): 1 2 3
8. Number of windows: _____
9. Number of bedrooms: _____
10. Total number of pets: _____
11. Total number of "furry" pets: _____
12. Type of primary heating (Please circle **ONLY** one choice that represents your most common practice):

    Wood stove Electrical Propane Natural gas furnace Oil Other: _____

13. Type of secondary heating (Please circle **ONLY** one choice that represents your most common practice):

    Wood stove Electrical Propane Natural gas furnace Oil Other: _____

14. Existing appliance(s): Fireplace Wood stove Furnace Wood stove insert
15. Wood stove model *(If you have access, information is located on the back of the stove)*:

    _____

16. Approximately how old is your wood stove:

    0-5 years old 6-10 years old 11-15 years old 16 + years old

17. Is your wood stove EPA-certified? Yes No I don't know

18. When was the last time you had your chimney cleaned?

    Less than 6 months ago 6-12 months ago 12-18 months ago more than 18 months ago

19. Within the last 12 months have you had wet or damp spots on surfaces inside your home other than in the basement (for example on walls, wall paper, ceilings or carpets)?

    Yes No I don't know

20. Has there been mold or mildew on any surfaces inside your home in the last 12 months?

    Yes No I don't know

Child Birth and Infancy Data

Date: _____

Technician:_____

Home ID #:_____

Child ID #:_____

Date of Birth: _____

Age: _____

Sex: _____

Birth weight: _____

Age of Mother at Birth: _____

Breastfed? (circle one) Yes No

If yes, for how long? _____

Has your child received the flu shot this year? (circle one) Yes No

If not, do you plan to have your child receive the flu shot? Yes No

Does your child attend: day care preschool/school

If yes, how many hours/day: _____ How many days/week: _____

Does your child have siblings in school or day care? Yes No

PARENT/CAREGIVER REPORTING OF SYMPTOMS - INSTRUCTIONS

We are asking you to help us in monitoring the health of your child. We would like you to contact us immediately if your child experiences any of the symptoms indicated below.

You can contact us through one of two ways:

1. **By email to KidsAIR@umontana.edu.**
2. **By voice message or text to 406-?????**

As part of your email, voice or text message please indicate a good time for us to call you back on that day or the next.

PLEASE NOTIFY US IF YOUR CHILD EXPERIENCES ANY OF THE FOLLOWING:

- Fever
- Rapid breathing
- Difficult breathing
- Noisy breathing
- Runny nose
- Cough
- Wheezing
- Doctor or health clinic visit for any of the above

Procedures for collection of child health measures (i.e., respiratory rate, saturated oxygen, temperature). Complete the Child Symptom Questionnaire and Health Measures Visit Sheet.

1. Make sure the child is comfortable with who you are and what you intend to do.
2. Explain your steps to them beforehand so they are aware.
3. Very young children may want to play with or touch your equipment as well, and it will most likely calm them if they do. Both instruments are rugged and can withstand being handled by them.

History/Symptoms

4. Make sure you have your Child Symptom Questionnaire handy for recording data.
5. Complete the questionnaire and record symptoms as stated by the caregiver. You can also make note of symptoms given by the child if they offer them up (but write them separately so you know which comments belong to whom). Record any important personal observations as well.

Health Measures

6. Per training with Dr. Paul Smith, complete the Health Measures Visit Sheet.
7. Count and observe respiratory rate and effort. It is best if the caregiver can hold the child on their lap with their shirt up. She can distract or comfort them while you observe. Determining respiratory rate can be easy if the child is distracted by something (like a toy or TV), or if the child is sleeping. With older children, or very attentive ones, it can be harder to observe their breathing rate without them noticing. If the child knows you are counting their breaths, they may adjust their breathing rate subconsciously. A good trick is to instead act like you are taking their pulse, and while they think you are feeling for their heartbeat at the wrist, you are instead subtly watching them inhale and exhale. You can also place a hand flat on the child's upper back to help feel inhalations and exhalations better.

    - When counting breaths, you will need to have a clock nearby.
    - Start counting breaths for 30 seconds and remember the number.
    - Take this number and multiply it by 2. This is the number of breaths per minute.
    - Record this observation in the Health Measures Visit Sheet.
    - Also note any retractions in the Health Measures Visit Sheet.

8. Now, take the child's temperature using the temporal thermometer. This thermometer simply touches their forehead, and is very noninvasive. See the EXERGEN Temporal Thermometer Protocol.
9. Chest auscultation for crackles, wheeze or stridor.
10. Determine the Oxygen saturation (SpO2) in the blood by using the Pulse Oximeter next. See the Pulse Oximeter Protocol. Do this last. Some kids hate it and crying will make the rest of your exam hard. Also record the pulse rate (PRbpm) off the SpO2.

CHILD SYMPTOM QUESTIONNAIRE

Home ID #_____ Child ID #_____

Date:_____ Data collected: By phone At home

In the last two weeks has your child been ill? No Yes

If yes, is child still ill? No Yes

Has your child seen a doctor or hospital or nurse for this illness? No Yes

If yes, indicate person/location:_____

Note: If provider is different from indicated on PHI form collected at initial visit, obtain a new parent signed PHI form.

Is your child taking any new medicines for this illness? No Yes

Medication Names

_____

_____

_____

Has your child had any of the following:

Fever?	No	Yes
		If yes, temperature?_____°F Indicate "N/A" if unknown.
Rapid breathing?	No	Yes
Difficult breathing?	No	Yes
Noisy breathing?	No	Yes
Runny nose?	No	Yes
Cough?	No	Yes
Wheezing?	No	Yes

[If data were collected by phone and child is currently ill, schedule home visit]

Health Measures Visit Sheet

Home ID #_____ Child ID #_____

Date:_____

Physical

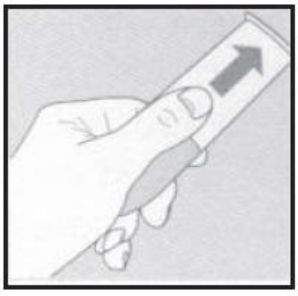
Lethargy Yes No	**RR** (bpm)	**Retractions** (score)	**Temperature °F**	**Lung sounds** Wheeze Stridor Crackles	**%SpO2**	**Heart Rate** (PRbpm)	**AHR**

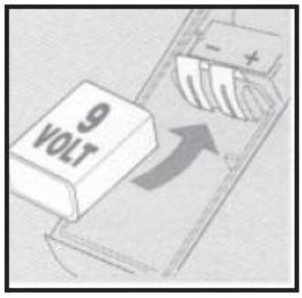
Referred? Yes No **If yes, indicate level of referral:** Emergent Urgent Recommended follow up with primary care provider

Note: For an Emergent or Urgent referral, follow referral procedures and then contact PI immediately.

EXERGEN Temporal Thermometer Protocol

1. Remove cap from the end of thermometer.
2. Make sure metal probe surface is shiny and clean.
    a. If not, use an alcohol swab to clean.
    b. Allow to dry.
3. Place probe end of thermometer flush to the center of child's forehead.
    a. Probe should be halfway between hairline and eyebrows.
4. With the probe placed, press the grey front button and hold.
    a. The thermometer will start beeping and a red LED on the back of the thermometer will turn on.
5. With the button still depressed, slide the thermometer from the center of the forehead left or right to the hairline.
    a. Keep the probe moving in a straight line—don't follow the hairline down toward the ear.
6. Release the grey button when you reach the hairline.
7. Your temperature measurement will show on the LED display.
8. Record temperature on Health Measures Visit Sheet.
9. Clean probe sensor area with an alcohol swab.
10. Allow to dry and reattach probe cap for travel.
11. To switch the battery, remove the back lower cover and exchange the 9V square battery.

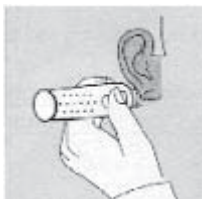




The thermometer will turn off on its own. To wake it back up, press the grey button once. The display will then show you the last measurement taken. If you continue to hit the grey button, it will scroll through the last eight measurements taken.

If the forehead has perspiration present, measure the temperature from behind the ear instead.

1. Instead of placing probe on center of forehead, place it on the neck just behind the ear lobe.
2. Press and hold grey button as before and take a reading while keeping the probe stationary in that spot.



Pulse Oximeter Protocol

1. Remove blue Pulse Oximeter (pulse-ox) from blue carrying case.
2. Squeeze the end of the pulse-ox that says PUSH to open the clip.
3. Place the child's index or thumb into the clip and release the pulse-ox so it gently squeezes the finger.
    a. The child's fingernail should be facing up, toward the display. Don't put the pulse-ox on upside down!
    b. Make sure the child is not moving and is at ease during this process.
4. Press the white button on the top and it will turn on and start to take a reading.
    a. You'll notice red LED lights show up on the display.
    b. The reading will take a few seconds before it shows up on the display.
    c. Once it's ready, you will see two numbers:
        i. The first number will appear about "PRbpm," which is your current Heart Rate
        ii. The second number appears above "%SpO2," which is your oxygen percentage.
    d. Wait at least 10 seconds after the first reading shows up before you record the numbers.
    e. Write the two measurements down on the Health Measures Visit Sheet.
5. Gently press the PUSH end of the pulse-ox again to open the clip and release the finger.
6. The pulse-ox will turn off on its own.
7. Use an alcohol swab to gently clean the inside of the clip.
8. You can store it back in its blue carrying case.

9. If the low battery icon shows up on the display, you need to switch out the batteries.
    a. Flip the pulse-ox over and slide off the blue battery cover.
    b. Replace the two AAA batteries.
    c. Replace the blue cover.

Referral Protocol

The outcomes targeted in the KidsAIR study are illnesses in children so it is anticipated that significant illness might be encountered. Epidemiologic data and other studies give evidence that such cases are few but ethically plans should be in place for field workers encountering them (RESPIRE studies, RSV statistics). In keeping with the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) in its report, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts* (http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf), the following outline describes our protocol for management of incidental illnesses in the subjects enrolled in the KidsAIR study.

1. The medical resources of specific areas will be determined by participating investigators prior to collection of any field data and that list of resources will be provided to each field worker in anticipation of emergent or urgent needs. That list will include local Emergency Medical Services, physicians and health care facilities. In some specific areas, families are served by health care aides or nurses and when that is the case those persons will be the first contact for non-emergent cases.
2. Local healthcare providers will be contacted prior to study initiation and made aware of the nature of the study and intent of the fieldworkers.
3. Educational sessions will be provided to each field worker outlining signs of serious illness for the age groups being studied (World Health Organization – IMCI program). Signs of illness will be categorized as life threatening (emergent), urgent, or recommended for scheduled evaluation by a health care provider. Each category of illness will initiate a different level of response.
    a. Emergency calls will be made to the closest available emergency personnel. The field workers will stay at the home until emergency personnel arrive.
    b. Urgent calls (non-emergency but needing care in less than 24 hours) will be made to the primary health care provider identified by the parents. Should the family have no such provider, the closest emergency room and health care provider will be contacted.
    c. For illnesses that do not require emergent or urgent care, the parents will be advised to contact their health care provider. The field data collector will volunteer to help families make contact with appropriate health care providers. A phone call to the family will be made the following day to ensure referral has been made.
4. The field worker will first discuss concerns for incidental findings with the parent or care provider and they will be asked if they have a health care provider. If time allows, that person or facility will be the first notified of possible need for medical care. If the child does not have a primary care provider, a list of possible medical care providers or institutions will be provided.

Referral Protocol (continued)

Emergent signs and symptoms - call for immediate assistance to 911 local EMS

- Not breathing
- Cyanosis (blue coloration to the skin)
- Unresponsive to stimulation
- Pulseless or thread, weak pulse
- Seizures

Urgent care (call to local health care aid or physician)

- Difficulty breathing – retractions involving use of neck muscles and lower chest
- Pulse oximetry less than 90%
- Respiratory Distress – wheezing, stridor, muffled voice, difficulty speaking
- Coughing up blood
- Listlessness
- Fever > 100.4 °F (<2 month)
  - > 102.2 °F (2 months – 12 months)
  - > 102.2 °F and ill appearing (>12 months)
- Active bleeding
- Stiff neck and signs of mental status change or fever

Recommend follow up with primary care provider within the next day

- Wheezing not responsive to home medications but little or no distress
- Prolonged fever (more than 2 days)
- Prolonged cough (> 3 days)
- Prolonged illness and not getting better (>1 week)

HOME CHARACTERISTICS DATA SHEET

Technician:_____ Home ID:_____ Winter (1,2,3,etc.):_____

Sampling Dates:_____ Date form completed:_____

To be completed by an adult resident once at the beginning of each winter.

1. Number of total residents in home: _____
2. Number of residents younger than 18 years of age: _____
3. Number of residents younger than 5 years of age: _____
4. Type of home: House Mobile Home Duplex/Apt Other: _____
5. Year home built: _____
6. Square footage of home: _____
7. Number of floors (not incl. bsmnt): 1 2 3
8. Number of windows: _____
9. Number of bedrooms: _____
10. Total number of pets: _____
11. Total number of "furry" pets: _____
12. Type of primary heating (Please circle **ONLY** one choice that represents your most common practice):

    Wood stove Electrical Propane Natural gas furnace Oil Other: _____

13. Type of secondary heating (Please circle **ONLY** one choice that represents your most common practice):

    Wood stove Electrical Propane Natural gas furnace Oil Other: _____

14. Existing appliance(s): Fireplace Wood stove Furnace Wood stove insert
15. Wood stove model *(If you have access, information is located on the back of the stove)*:

    _____

16. Approximately how old is your wood stove:

    0-5 years old 6-10 years old 11-15 years old 16 + years old

17. Is your wood stove EPA-certified? Yes No I don't know

18. When was the last time you had your chimney cleaned?

    Less than 6 months ago 6-12 months ago 12-18 months ago more than 18 months ago

19. Within the last 12 months have you had wet or damp spots on surfaces inside your home other than in the basement (for example on walls, wall paper, ceilings or carpets)?

    Yes No I don't know

20. Has there been mold or mildew on any surfaces inside your home in the last 12 months?

    Yes No I don't know

HOME ACTIVITY LOG

Technician:
Home ID:
Winter (1,2,3,etc.):
Sampling Day (1 – 6):
Sampling Date:

To be completed by an adult resident for each day of six day sampling visit.

1. Were any of the following heating appliances, other than your woodstove, used in the home during the sampling period?

• Gas	No	Yes
• Electrical	No	Yes
• Propane	No	Yes
• Oil	No	Yes
• Other, specify:___	No	Yes

2. Did any of the following activities or conditions occur in the home during the sampling period?

• Smoking by anyone in the home (cigarette, pipe, or other)	No	Yes
• Incense burning	No	Yes
• Candle burning	No	Yes
• Kerosene/oil lamp	No	Yes
• Open windows	No	Yes
• Front door propped open	No	Yes
• Dusting/sweeping/vacuuming	No	Yes

WOOD STOVE USAGE LOG

Technician:
Home ID:
Winter (1,2,3,etc.):
Sampling Dates:
Date form completed:

To be completed by an adult resident at the end of each six day sampling visit.

1. During the sampling period, how would you describe the level of wood burning compared to a typical winter day (circle one):

   No burning Light burning Average burning Heavy burning

2. What kind of wood was used or was used most frequently? *Please choose **ONLY** one*.

   Lodgepole Pine Ponderosa Pine Fir Larch

   [LIST OTHER COMMON TYPES] _____

3. When do you get your wood before burning? (Please circle **ONLY** one choice that represents your most common practice)

   A few days Between 1 week and 1 month

   Between 1 month and 3 months Between 3 months and 6 months

   Between 6 months and 1 year More than 1year

4. On average, how many cords of wood do you burn each year? _____ cords

5. How do you usually acquire your wood? (Please circle **ONLY** one choice that represents your most common practice)

   Harvest yourself Purchase it Other:_____

Revised October 13, 2014

IN HOME LOG

Technician:
Home ID:
Child ID:
Winter:
Sampling dates:
Sampling start time:

To be completed by an adult resident for each participating child for each 24 hour period of six day sampling visit.

For each row, please mark the day of week (M, T, W, Th, F, Sa, Su) and whether your child was or was not home. If your child was not at home, please mark the circle indicating where your child was.

Age of participating child: _____
Child is a: girl boy

Day	Day of week	Time			At home?		If not home, where?				
							school	day care	relative's house	friend's house	other
1		7:00 AM	to	8:00 AM	Y	N					
1		8:00 AM	to	9:00 AM	Y	N					
1		9:00 AM	to	10:00 AM	Y	N					
1		10:00 AM	to	11:00 AM	Y	N					
1		11:00 AM	to	12:00 PM	Y	N					
1		12:00 PM	to	1:00 PM	Y	N					
1		1:00 PM	to	2:00 PM	Y	N					
1		2:00 PM	to	3:00 PM	Y	N					
1		3:00 PM	to	4:00 PM	Y	N					
1		4:00 PM	to	5:00 PM	Y	N					
1		5:00 PM	to	6:00 PM	Y	N					
1		6:00 PM	to	7:00 PM	Y	N					
1		7:00 PM	to	8:00 PM	Y	N					
1		8:00 PM	to	9:00 PM	Y	N					
1		9:00 PM	to	10:00 PM	Y	N					
1		10:00 PM	to	7:00 AM	Y	N					

Home ID:
Child ID:
Winter:
Sampling dates:
Sampling start time:

Day	Day of week	Time			At home?		If not home, where?				
							school	day care	relative's house	friend's house	other
2		7:00 AM	to	8:00 AM	Y	N					
2		8:00 AM	to	9:00 AM	Y	N					
2		9:00 AM	to	10:00 AM	Y	N					
2		10:00 AM	to	11:00 AM	Y	N					
2		11:00 AM	to	12:00 PM	Y	N					
2		12:00 PM	to	1:00 PM	Y	N					
2		1:00 PM	to	2:00 PM	Y	N					
2		2:00 PM	to	3:00 PM	Y	N					
2		3:00 PM	to	4:00 PM	Y	N					
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2		5:00 PM	to	6:00 PM	Y	N					
2		6:00 PM	to	7:00 PM	Y	N					
2		7:00 PM	to	8:00 PM	Y	N					
2		8:00 PM	to	9:00 PM	Y	N					
2		9:00 PM	to	10:00 PM	Y	N					
2		10:00 PM	to	7:00 AM	Y	N					
3		7:00 AM	to	8:00 AM	Y	N					
3		8:00 AM	to	9:00 AM	Y	N					
3		9:00 AM	to	10:00 AM	Y	N					
3		10:00 AM	to	11:00 AM	Y	N					
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3		7:00 PM	to	8:00 PM	Y	N					
3		8:00 PM	to	9:00 PM	Y	N					
3		9:00 PM	to	10:00 PM	Y	N					
3		10:00 PM	to	7:00 AM	Y	N					

Home ID:
Child ID:
Winter:
Sampling dates:
Sampling start time:

Day	Day of week	Time			At home?		If not home, where?				
							school	day care	relative's house	friend's house	other
4		7:00 AM	to	8:00 AM	Y	N					
4		8:00 AM	to	9:00 AM	Y	N					
4		9:00 AM	to	10:00 AM	Y	N					
4		10:00 AM	to	11:00 AM	Y	N					
4		11:00 AM	to	12:00 PM	Y	N					
4		12:00 PM	to	1:00 PM	Y	N					
4		1:00 PM	to	2:00 PM	Y	N					
4		2:00 PM	to	3:00 PM	Y	N					
4		3:00 PM	to	4:00 PM	Y	N					
4		4:00 PM	to	5:00 PM	Y	N					
4		5:00 PM	to	6:00 PM	Y	N					
4		6:00 PM	to	7:00 PM	Y	N					
4		7:00 PM	to	8:00 PM	Y	N					
4		8:00 PM	to	9:00 PM	Y	N					
4		9:00 PM	to	10:00 PM	Y	N					
4		10:00 PM	to	7:00 AM	Y	N					
5		7:00 AM	to	8:00 AM	Y	N					
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5		6:00 PM	to	7:00 PM	Y	N					
5		7:00 PM	to	8:00 PM	Y	N					
5		8:00 PM	to	9:00 PM	Y	N					
5		9:00 PM	to	10:00 PM	Y	N					
5		10:00 PM	to	7:00 AM	Y	N					

Home ID:
Child ID:
Winter:
Sampling dates:
Sampling start time:

Day	Day of week	Time			At home?		If not home, where?				
							school	day care	relative's house	friend's house	other
6		7:00 AM	to	8:00 AM	Y	N					
6		8:00 AM	to	9:00 AM	Y	N					
6		9:00 AM	to	10:00 AM	Y	N					
6		10:00 AM	to	11:00 AM	Y	N					
6		11:00 AM	to	12:00 PM	Y	N					
6		12:00 PM	to	1:00 PM	Y	N					
6		1:00 PM	to	2:00 PM	Y	N					
6		2:00 PM	to	3:00 PM	Y	N					
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6		6:00 PM	to	7:00 PM	Y	N					
6		7:00 PM	to	8:00 PM	Y	N					
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6		9:00 PM	to	10:00 PM	Y	N					
6		10:00 PM	to	7:00 AM	Y	N					
7		7:00 AM	to	8:00 AM	Y	N					
7		8:00 AM	to	9:00 AM	Y	N					
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7		12:00 PM	to	1:00 PM	Y	N					
7		1:00 PM	to	2:00 PM	Y	N					
7		2:00 PM	to	3:00 PM	Y	N					
7		3:00 PM	to	4:00 PM	Y	N					
7		4:00 PM	to	5:00 PM	Y	N					
7		5:00 PM	to	6:00 PM	Y	N					
7		6:00 PM	to	7:00 PM	Y	N					
7		7:00 PM	to	8:00 PM	Y	N					

End of Winter Questionnaires

Education Homes:

1. Post winter Questionnaire Education Homes
2. KAB Education Homes Post Winter 1 & 2 Assessment

Filter Homes:

1. Post winter Questionnaire Filter Homes
2. KAB Filter Homes Post Winter 2 Assessment

Post Winter Questionnaire - Education Homes

Home ID: _____ Technician: _____

Date: _____

Filled out by: Mother Father Other: _____

Please complete the following brief survey regarding your experiences this winter. Please circle your response below each item.

1. How often did you use the moisture meter during this winter?

   Never Once Once a Month Weekly Daily

2. Did you split the wood and take the reading from the freshly cut portion of the log?
   Yes No Not Applicable

3. How easy has it been to use the moisture meter?

   Difficult Somewhat Difficult Somewhat Easy Easy Not Applicable

4. Has the moisture meter been helpful to you this winter?

   Not Helpful Not Very Helpful Somewhat Helpful Very Helpful
   If it was not helpful, can you tell us why?
   _____
   _____

5. How often did you use the wood stove thermometer during this winter?

   Never Once Once a Month Weekly Daily

6. How easy has it been to use the wood stove thermometer?

   Difficult Somewhat Difficult Somewhat Easy Easy Not Applicable

7. Has the wood stove thermometer been helpful to you this winter?

   Not Helpful Not Very Helpful Somewhat Helpful Very Helpful
   If it was not helpful, can you tell us why?
   _____
   _____

8. How often did you use the firestarters during this winter?

   Never Once Once a Month Weekly Daily

9. How easy has it been to use the firestarters?

   Difficult Somewhat Difficult Somewhat Easy Easy Not Applicable

10. Have the firestarters been helpful to you this winter?

    Not Helpful Not Very Helpful Somewhat Helpful Very Helpful

    If it was not helpful, can you tell us why?

    _____
    _____

11. How often did you recall or watch the educational videos during this winter?

    Never Once Once each Month Weekly

12. How easy has it been to use the guidelines included in the educational videos?

    Difficult Somewhat Difficult Somewhat Easy Easy Not Applicable

13. Have the guidelines included in the educational videos been helpful to you this winter?

    Not Helpful Not Very Helpful Somewhat Helpful Very Helpful

    If it was not helpful, can you tell us why?

    _____
    _____

14. Our staff called you at least once a month throughout the study to check in on your child's health and to ask a few questions about your wood stove. Were these phone calls helpful with troubleshooting issues regarding your wood stove?

    Not Helpful Not Very Helpful Somewhat Helpful Very Helpful

    If these calls were not helpful, can you tell us why?

    _____
    _____

15. Was there anything new/interesting/helpful that you learned this winter about burning more efficiently and/or cleaner with your wood stove?

    _____
    _____
    _____
    _____

KAB - Education Homes - Post Winter 1 & 2 Assessment

Home ID: _____ Date: _____

Filled out by: Mother Father Other: _____

The following questions will help us learn more about your woodstove use habits and behaviors. There are no "right or wrong" answers to these items. This information will help us understand how useful the educational materials and videos were for you this winter. Please rank the following items in terms of how important, helpful, and useful the following suggestions were when you used your wood stove the past winter.
Please rank the items on a scale of 1-4
(1 = not important at all, 2= not very important, 3 = somewhat important, 4 = very important)

During the past year how important has it been:

- To split your firewood in smaller sizes (6 inches or less in diameter)? _____
- To store your firewood in a covered wood pile? _____
- To season firewood for 6-12 months before burning? _____
- To use a moisture meter to test your wood? _____
- To only burn dry, seasoned wood (moisture content <20%)? _____
- To maintain a bed of ash just below the vent holes of the wood stove? _____
- To crack a window/door on the same level when starting a fire? _____
- To use dry kindling, air movement, and fire starters to help you start a hot fire? _____
- To allow small hot fires that burn for 20 to 30 minutes to reach optimal burn temperatures? _____
- To use a wood stove thermometer to help you burn at specific desired temperatures _____
- To check your wood stack 20-30 minutes after starting to burn? _____
- To allow the fire to burn for 20-30 minutes before refueling? _____
- To not burn items other than wood (e.g., trash, cardboard, etc.)? _____
- To clean your flue and chimney? _____
- To condition or dry wood inside for 2 days before burning? _____
- To determine wood stove model and locate manual _____

Post Winter Questionnaire - Filter Homes

Home ID: _____ Technician: _____
Date: _____
Filled out by: Mother Father Other: _____

Please complete the following brief survey regarding your experiences this winter. Please circle your response below each item.

1. Did you use your Filter unit this winter? Yes No

2. Did you use your Filter unit continuously throughout the winter? Yes No

3. If you did not use your Filter unit continuously, approximately how many hours per week did you have your Filter unit turned on?_____

4. On what setting(s) did you use your Filter unit when you had it turned on? Please indicate the percentage of time on each setting below:

   High_____ Medium_____Low_____

5. If you decided not to use the Filter unit, what were the reasons?

   Noise Cost Appearance Space Concerns Inconvenience N/A

   Other _____

   Other_____

6. Of the reasons above, which was the most important reason?

   _____ N/A

7. Overall, do you think the Filter unit has been helpful to you and/or your family this winter?

   Not Helpful Not Very Helpful Somewhat Helpful Very Helpful

KAB - Filter Homes - Post Winter 2 Assessment

Home ID: _____ Date: _____

Filled out by: Mother Father Other: _____

The following questions will help us learn more about your woodstove use habits and behaviors. There are no "right or wrong" answers to these items. This information just helps us understand your woodstove usage. Please rank the following items in terms of how important these factors are when you have used your wood stove the past two years.
Please rank the items on a scale of 1-4
(1 = not important at all, 2= not very important, 3 = somewhat important, 4 = very important)

During the past two years how important has it been:

- To split your firewood in smaller sizes (6 inches or less in diameter)? _____
- To store your firewood in a covered wood pile? _____
- To season firewood for 6-12 months before burning? _____
- To use a moisture meter to test your wood? _____
- To only burn dry, seasoned wood (moisture content <20%)? _____
- To maintain a bed of ash just below the vent holes of the wood stove? _____
- To crack a window/door on the same level when starting a fire? _____
- To use dry kindling, air movement, and fire starters to help you start a hot fire? _____
- To allow small hot fires that burn for 20 to 30 minutes to reach optimal burn temperatures? _____
- To use a wood stove thermometer to help you burn at specific temperatures? _____
- To check your wood stack 20-30 minutes after starting to burn? _____
- To allow the fire to burn for 20-30 minutes before refueling? _____
- To not burn items other than wood (e.g., trash, cardboard, etc.)? _____
- To clean your flue and chimney? _____
- To condition or dry wood inside for 2 days before burning? _____
- To determine wood stove model and locate manual? _____

Statistical Analysis Plan

Analysis was conducted using R version 3.6.2 (The R Foundation for Statistical Computing, Austria). We calculated descriptive statistics for continuous variables (n, mean, standard deviation [sd], minimum [min], median, maximum [max]) and categorical variables (n, percentage of total) across all study households and separately for each treatment arm and study area. We averaged indoor concentrations of PM2.5 over the 6-day sampling period for each home and for the times during which each child was reported as being at the household.

Primary analyses were conducted within three model frameworks using the lme4 package (Bates et al. 2015): 1) intent-to-treat (ITT) framework with LRTI outcome (ITT-LRTI), 2) ITT framework with PM2.5 outcome (ITT-PM2.5), and 3) exposure-response (ER) framework with LRTI as the outcome and PM2.5 as the exposure of interest. Although LRTI cases were collected as count data, very few children had more than one LRTI, resulting in under-dispersed data that violated the assumptions of attempted Poisson and negative binomial regression models. Thus, the ITT-LRTI framework utilized mixed effects logistic regression models (using the glmer function) with presence of LRTI (yes or no) as the outcome and assigned treatment as the exposure of interest. The ITT-LRTI models included a covariate for person-time at risk to account for the wide variability of child-weeks at risk across study participants. The models also included a covariate for child age (<1 year vs. 1 to 4 years) since randomization occurred within strata of this term. A nested random term (i.e., household:cohort:area) was included in the model to account for repeated measures clustered within household, cohort, and study area. The ITT-PM2.5 framework used mixed effects linear models (using the lmer function) with mean 6-day indoor PM2.5 concentration as the outcome and assigned treatment as the exposure of interest. Models were adjusted for child age and included a nested random term of cohort:area (there were no repeated measures within household for PM2.5). Both ITT models utilized the study's randomization and were not adjusted for potential confounding variables in the primary analyses.

The ER framework utilized mixed effects logistic regression models (using the glmer function) with presence of LRTI (yes or no) as the outcome and mean 6-day indoor PM2.5 concentration as the exposure of interest. As with the ITT-LRTI models, ER models were adjusted for person-time at risk and included a nested random term (i.e., household:cohort:area) to account for repeated measures in the analysis. In addition, since the ER models did not utilize the study's randomization to help control for confounding, covariates were included in the model to adjust for potential confounders. Confounders were identified a priori through previous literature and by assessing independent associations with the exposure and outcomes of interest (Adaji et al. 2019; Mortimer et al. 2017; Noonan et al. 2019; Smith et al. 2011; Walker et al. 2021). We also used directed acyclic graphs (DAGs) to assess the direction and potential relationship between indoor PM2.5, LRTI, and covariates (Figure S3). Final ER models were adjusted for child age and sex, caregiver race and sex, household income, caregiver education, if a household resident smoked, and ambient temperature and PM2.5.

The primary ITT model framework was prespecified in our previously published methods paper (Noonan et al. 2019). We conducted a number of sensitivity analyses in all model frameworks that were specified a priori (during the initial model development when the analyst was masked to treatment arm assignment) and assessed the impact of including potential confounders in the models and using subsets of the data. We conducted sensitivity analyses by including potential confounders that had some imbalance across study arms (ITT frameworks) or by including additional potential confounders not included in the primary model (ER framework). Due to the different control treatment in AK (no filtration unit), we conducted the ITT-LRTI and ITT-PM2.5 analyses with AK households excluded from the dataset. For the ITT-LRTI and ER frameworks, we also conducted a sensitivity analysis with a dataset restricted to Winter 1 only, as this was the only winter of observation when indoor PM2.5 was sampled. For the ER framework we conducted an additional sensitivity analysis that used indoor PM2.5 when each child was at home as the primary exposure variable in place of indoor PM2.5 over the entire sampling period.

We also conducted some post hoc sensitivity analyses for the ITT-LRTI framework with other model variations to provide insight into our primary model selection and results. Specifically, we assessed models that 1) used

study area (AK, NN, WMT) as a fixed effect rather than a random nested term, 2) removed the covariate for person-time at risk, and 3) removed the random nested term for household.

We evaluated potential modification of the effect of the treatments by a priori selected child, caregiver, and home characteristics within each of the model frameworks by including interaction terms in the primary model. We assessed significance of the interaction terms using Type II Wald Chi-square tests. Model assumptions were evaluated in all analysis frameworks. Indoor PM2.5 concentrations were natural-log transformed in the ITT-PM2.5 framework, and estimates are presented as percent difference in geometric mean PM2.5.