COVER PAGE

For

Informed Consent Template

(yellow-highlighted areas replaced by local context for each site)

ICF /IRB Study Title

The BREATHE Study: Bronchiolitis Recovery and the Use of High Efficiency Particulate Air (HEPA) Filters

NCT study title: Bronchiolitis Recovery and the Use of High Efficiency Particulate Air (HEPA) Filters

Clinicaltrials.gov number:
NCT05615870

UAMS IRB (cIRB) ICF approval date for template version 05:
30-August-2023

Key Information for

The Breathe Study: Bronchiolitis Recovery and the Use of High Efficiency Particulate Air (HEPA) Filters

This first 3 pages of this form give you key information to help you decide if you want to allow your child to join the study. We will explain things in more detail later in this form.

We are asking if you want to volunteer your child for a research study to see if using a portable air purifier (HEPA filter system) affects the health of children who have been hospitalized with bronchiolitis. Bronchiolitis is an illness that is usually caused by a virus. It can make breathing hard.

Air purifiers remove small particles from the air. These small particles can go into the lungs and also affect breathing.

The study team hopes to learn if children who have been in the hospital with bronchiolitis do better if they return home to a residence with an air purifier. The researchers want to know if an air purifier helps to decrease symptoms like coughing and wheezing.

The study will have 2 groups. One group, the active group, will get air units with HEPA (high efficiency particulate air) filters in them. These air units with filters are the air purifiers. The other group, the control group, will get units without filters in them. The units without filters do not clean the air.

> *For the rest of this consent, we will use "air unit" to mean either the air purifier unit (with the HEPA filter) or the unit without any filter.*

The chance of your child being in either group is like flipping a coin. Your child has the same chance of being in either group. Neither you nor your doctor will know if your child is in the active group or in the control group. After your child has finished the study, all participants in both groups will get to keep the air units. All participants will also get HEPA filters to put in their air units. This means that all units will be active (purifier) units after the study.

Please ask the research team if you have any questions about anything in this form. If you have questions later, contact the researcher in charge of the study at your site. Contact information is on page 2 of this form.

What will happen if I allow my child to join the study?

If you allow your child join, you will being providing information on behalf of your child. Your part in this research will last about 6 months (26 weeks). Your part will take up to 25 hours. These 25 hours will be spread out over your 26-week participation.

During the study, we will ask that you

- Provide information about your child's health
- Set up and use the air units provided by the study team. The study team will help you with the set up.
- Provide information weekly. This will include information about child and your air unit.

Additional information is provided in the detailed section of this form

Do I have to allow my child to join this study?

No. It is okay to say no. Neither you nor your child will not lose any services, benefits, or rights either of you would normally have if you decide not to allow your child to join. If you decide to allow your child to take part in the study, it should be because you really want to volunteer for your child.

What do I need to know to decide if I should join this study?

People decide to join studies for many reasons. Here are some of the main things you should think about before choosing to allow your child to be part of this study.

Main reasons to join the study

- ✓ This study will help the researchers find out if babies who had bronchiolitis might be helped by a simple, portable, air purification system (air filter system).

Main reasons <u>not</u> to join the study

- ✓ Your child may not benefit from being in this study.
- ✓ Your child may be in the control group and not have purified air until 6 months after you enroll your child.
- ✓ Unless the study team notices a problem, you will not know the air quality results from your home until your child has finished his/her study participation. You will receive air quality results <u>before</u> your child's end of participation only if your air quality data can be transmitted through wireless methods <u>and</u> if continued poor air quality is noticed early in your child's study participation. <u>After</u> your child completes his/her study participation, the study team will create a report containing your home's air quality. All participants will get a report. The study team will tell you if unusually poor air quality was noticed at any time during your participation.

These are just some of the reasons to help you decide if you want to allow your child to join the study. We will explain more about the risks, benefits, and other options to joining the study later in this form.

Tell the study team if you decide that you do not want your child to be in the study. Remember, it is okay to say no. Your child can still get his/her medical care from <insert local institution name> if he/she is not in the study.

Contact Information:

<insert local contact information, specifically, site investigator name, site investigator address (for receiving opt-out letters), and telephone number; include email if desired>

<insert local institution name>

Informed Consent Form

- **We are asking you to allow your child to be in a research study. You do not have to allow your child to be in the study.**
- **Your child can still get his/her medical care from <insert local institution name> even if your child is not in the study.**
- **Take as much time as you need to read this form and decide what is right for your child.**

Why am I being asked to allow my child to be in this research study?

- We want to learn more about how to help infants who have been hospitalized with bronchiolitis. Bronchiolitis is caused by a virus. After going to the hospital for bronchiolitis, some infants have more coughing, wheezing, and trouble breathing than infants who did not have to go to the hospital.
- By doing this study, we hope to find out air purifiers help infants who have been in the hospital for bronchiolitis. We hope to find out if infants with air purifiers in use in their homes have less respiratory symptoms and less medical visits for breathing symptoms than infants who do not have air purifiers in use in their homes.
- We also want to find out what affect the air purifier has on the quality of the air in homes.
- We are asking people like your child, who has been in the hospital for bronchiolitis, to help us.
- There will be approximately 228 children in this study. All children will be < 1 year old when they start the study. Children will be recruited from approximately 17 different hospitals that are associated with the IDeA States Pediatric Clinical Trials Network.

What if I don't understand something?

- This form may have words you do not understand. If you would like, research staff will read it with you.

- You are free to ask questions at any time – before, during, or after your child is in the study.
- Please ask as many questions as you would like before you decide if you want to allow your child to be in this study. If you decide to allow your child to take part in the study, it should be because you really want to volunteer on behalf of your child.

What will happen if I say yes, I want my child to be in this study?

First, we will see if your child qualifies to be in the study. The study team may have already reviewed parts of your child's medical record to see if he/she qualifies for the study, but will ask questions to be sure. The initial medical record review to see if your child qualified for the study was approved by the IRB.

- To qualify your child must
  - Have been in the hospital for bronchiolitis. This must be the 1st time your child has been in the hospital for bronchiolitis.
  - Be less than 12 months old at hospital admission
  - Have 1 main home (where child lives at least 5 days each week)
  - Have parent/legal guardian (person who will answer on behalf of child) who speaks English or Spanish
  - Live in a home with electricity and that has internet or cellular access services
- Your child CANNOT be part of the study:
  - If your child has a chronic airway or respiratory condition requiring home oxygen, mechanical ventilation, or a tracheostomy. A tracheostomy allows for the use of a special breathing tube to help someone get air into his/her lungs.
  - If your child has certain types of chronic medical conditions that affect their immune system, heart, lungs, or ability to breathe, or if your child is eligible to receive palivizumab (also called Synagis)
  - If your child is already enrolled or plans to enroll in any other research study for bronchiolitis treatment(s)
  - If someone who regularly stays in the house smokes, vapes, or uses e-cigarettes inside or outside the house
  - Air purifiers (HEPA filtration units) are already in use in your home

- If you plan to move from your home in the next 6 months
  - If another child in your household is already enrolled in this study

- If your child qualifies, we will do these things:
  - Ask if you agree to
    - Track your child's respiratory symptoms every day
    - Talk to a study team member each week for the first four weeks and at least monthly after that. Contact may be more frequent if needed.
    - Complete a short weekly survey
    - Install and run 2 air quality monitors, which we will provide
    - Install and run 2 air units, which we will provide
  - Ask you to sign this consent form. Your child cannot be in this study if you do not sign this form. No research activity will be done with your child if you do not sign this consent form
  - Ask you to provide information about your child and your child's home. This information includes:
    - Basic information about your child, (such as contact information and child's name, age, gender, race/ethnicity)
    - Health history information for your child (such as medications and family history of asthma)
    - Information about the child's home (such as primary heating source, type of cook stove, furry pets, etc.)
    - You do not have to answer certain questions if you do not want to. Examples of questions you do not have to answer: questions about race/ethnicity or questions about your own or your family's health
  - Provide a list of equipment you will be using and instructions for the equipment. Attachment 1 at the end of this consent has pictures of the equipment will you be using.
  - Provide information that may help you improve the quality of the air inside your/your child's home
  - Assign your child to either the active group or the control group, as described on page 1 of this consent.

- **Study Activities**
  - Weeks 1-2:

    You will be asked:

    - At Study Start Only to:
      - ✓ Set up the air quality monitor and air unit systems. This is a 1-time process and will be done with the help of the study team. It may take up to 2 hours to complete.
    - Daily to:
      - ✓ Record your child's symptoms (if any) in the Symptom Recall Tool. This will take about 5 minutes per day
    - Weekly to:
      - ✓ Give the Symptom Recall Tool information to the study team member. This may be done by phone or you may send it electronically
      - ✓ Report to the study team certain medical events that have happened since hospital discharge
      - ✓ Weekly activities will take about 15 minutes per week

  - Weeks 3-26:

    You will be asked:

    - Daily to:
      - ✓ Record your child's symptoms (if any) in the Symptom Recall Tool. This will take about 5 minutes per day
    - Weekly to:
      - ✓ Give the Symptom Recall Tool information to the study team member. This may be done by phone or you may send it electronically
      - ✓ Report to the study team certain medical events that have happened within the last week
      - ✓ Weekly activities will take about 15 minutes per week

- Week 26:

  In addition to above (for weeks 3-26), you will be asked to

  - complete a quality of life questionnaire. A study team member will help you.

    The questions are about your child's physical activities (energy levels), physical symptoms (skin, respiratory, gastrointestinal), emotional status (crying, sleeping, feelings of fear and attachment), social functioning (interactions with others) and cognitive functioning (speech, sound, expression and actions)
  - send back air quality monitor (PurpleAir) with internal SD card, WiFi hotspot, kW meter, and PurpleAir and hotspot charging cords
  - Total time for week 26 activities will be approximately 1 to 2 hours

How long will my child be in this study?

Your child will be in the study for 6 months. It will include reporting to the study team. You will report information on behalf of your child. You will report according to the schedule given in the "Study Activities" part of the section above.

What if I say no, I do not want my child to be in this study?

- Nothing bad will happen because of what you decide.
- Your child can still get medical care at <insert local institution name>

What happens if I say yes but change my mind later?

- Your child can stop being in the study at any time.
- Nothing bad will happen because you change your mind and your child leaves the study.
- Your child can still get medical care at <insert local institution name>.
- If you decide to stop allowing your child to be in the study, you must tell your site investigator in writing. Additional information is in the companion HIPAA research authorization.
  - You will be asked to send back the PurpleAir monitor, WiFi hotspot, kilowatt meter (all shown in Attachment 1 at the end of this consent), and the charging cords for the PurpleAir and hotspot. You will need to do this to get the reimbursement payment.

- You will keep the Healthy Homes Kit, the air units and filters (you will get active filters to use even if your child was assigned to the control group), the power cords, the tape measure, and the backpack.

Will it cost me anything to allow my child to be in the study?

The study will not cost you anything. You or your insurance company will be responsible for the costs of your child's regular medical care, as usual.

Will I be paid for being in the study?

Yes. You will receive several types of compensation.

(1) Healthy Homes Kit - for joining the study

a. This includes a tote bag; inside the bag there will be children's book(s), outlet & doorknob covers, cabinet/door latches, bath thermometer, carbon monoxide detector, bed bug traps, and green cleaning supplies

b. This is to thank you for joining the study and is yours to keep even if you later take your child out of the study

c. Value: approximately $42.00

(2) Backpack – used to send home some of the study equipment

a. This is yours to keep even if you later take your child out of the study

b. Value: approximately $22.00

(3) Air purifier units and filters plus associated items

a. At the end of study you will keep the 2 air purifiers units and will receive 2 sets of active filters (1 filter set per unit)

b. You will keep 4 power cords & a power adapter

c. You will keep the tape measure

d. Total value (filters, cords, tape measure): approximately $719.00

(4) Reimbursement for time and expenses and return of monitoring equipment

a. Baseline history	$ 5.00
b. Weekly reports submitted	$20.00 per week ($520 maximum)
c. Week 26 history	$ 5.00
d. Week 26 questionnaire	$10.00

e. Week 26 equipment* return $40.00

f. Electricity reimbursement $15.00

**Equipment = PurpleAir monitor with internal SD card, WiFi hotspot, kW meter, and PurpleAir and hotspot charging cords*

For your reimbursement for your time and expenses:

You will be paid <insert local context mechanism of payment> approximately once each month. If you change your mind and decide not to allow your child to be in the study, you will only be paid for the parts you submitted. You will still be able to keep the items listed in (1) through (3) above.

If you submit all forms and return the equipment, the maximum payment from (4) above will be $595 (for time and electricity).

The total maximum value, including all of above (including kit, purifiers & filters, reimbursement for time, etc.) is approximately $1,378.00

If you get more than $600 in one year (January-December) from <insert local institution making payment>, we may send you a tax form if the law requires it.

Will being in this study help my child in any way?

Being in the study may or may not help your child, personally. But even if it does not help your child, it may help other children with bronchiolitis in the future. What we learn may help in the following ways:

- This study will help the researchers find out if babies who had bronchiolitis might be helped by a simple, portable, air purification system (air filter system).
- You will get information about the quality of air in your house.

What are the risks of being in this study?

This is a minimal risk study. The risks of being in this study are no more than you/your child have in everyday life.

The risks of joining this study are:

- The false sense that the air unit will improve the quality of air in all areas of your home.
- The noise from the portable air unit could bother you or other family members.
  - Noise level could cause hearing problems if air unit not used as directed. For example, hearing problems could occur if the air unit is always too close to your

child or if the fan is routinely used at a higher setting than the study instructions recommend.

- The air unit may take up space. You might find this inconvenient.
- If the equipment is not used as directed, household members could be injured or get an electrical shock during installation or use in the home.
- The adhesive strips (Command™ hooks or similar) used to hold air quality monitors in place could damage the wall or other surface when the strips are removed.

There is also the risk that someone could find out that your child was in the study. They could learn something about your child that you do not want others to know. We will do our best to protect your/your child's privacy. Privacy protections are explained in more detail later in this form.

What if my child gets sick or hurt while he/she is in this study*?*

- If your child gets hurt or sick, and you think it is because of the study, do these things:
  - ✓ call your doctor – or if an emergency, call 911
  - ✓ give your doctor or ER staff
    - the name of this study, *The BREATHE Study*: *Bronchiolitis Recovery and the Use of High Efficiency Particulate Air (HEPA) Filters*
    - the name of the principal site investigator, <insert site investigator name>, for this study
    - a copy of this form if you have it
  - ✓ call <insert name of site investigator> at <provide phone number and 24 hr phone number>
- This treatment will be billed to you or your insurance company. No other form of payment is available.
- <additional local context information – if applicable>

Reminder: You do not give up any of your or your child's legal rights by agreeing to allow your child to be in this study or by signing this form or the companion HIPAA research authorization form.

What are the alternatives to being in this study?

You do not have to allow your child to be in this study.

The alternative to being in this study is to install a HEPA (high efficiency particulate air) filtration system yourself in your home.

Can my child be taken out of the study even if I want my child to continue?

Yes, the study doctor (or head researcher) can take your child out of the study if:

- You do not follow study instructions.
- It is not in your child's best interest to continue.
- The study is stopped for any reason.

What information will be collected about me and my child in the study?

During the study, we will need to learn private things about you/your child, including

- General contact and background information about you/your child. Examples: name, address, and telephone number.
- Medical information about your child. Examples: respiratory symptoms, healthcare visits, and medications.
- Personal information. Examples: race, gender, parents' education level, and home characteristics (e.g., wood stove use).
    - You do not need to answer any personal information questions you do not want to answer.

Who will see this information? How will you keep it private?

- The local study team will know your/your child's name and have access to your child's information.
- We will do our best to make sure no one outside the study knows your child is part of the study.
- We will take your/your child's name off information that we collect from you during the study. We will give your/your child's information a code, so that no one outside of this study can identify you/your child.
- We will share your/your child's study information with the sponsor, the Data Coordinating and Operations Center (DCOC) of the IDeA States Pediatric Clinical Trial Network (ISPCTN). This may include your/your child's name or other information that could be used to identify you or your child. You/your child's identifying information will only be shared if needed to make sure the study is being done properly.

- When we share the results of the study, e.g., in medical journals or in government databases, we will not include your or your child's name or anything else that could identify you or your child.
- There are people who make sure the study is run the right way. These people may see information that identifies you. They are:
  - ✓ National Institutes of Health (NIH), who is funding this study
  - ✓ OHRP (Office for Human Research Protections), a federal agency
  - ✓ UAMS Institutional Review Board (IRB)
  - ✓ Other UAMS institutional oversight offices
  - ✓ IDeA States Pediatric Clinical Trial Network (ISPCTN) Data Coordinating and Operations Center (DCOC)
  - ✓ Auditors and/or monitors working on behalf of the ISPCTN DCOC, the UAMS IRB, or NIH
  - ✓ Local IRB
  - ✓ Local institutional oversight offices
  - ✓ <additional local context>
- People at the University of Montana will
  - have your/your child's name and contact information so that they can send study equipment to you
  - receive and process air quality information from the PurpleAir monitors
- <insert local context – example for Arkansas follows> State law also requires us to report to the Arkansas Department of Health cases of certain diseases that a sick person could give to someone else. If we learn you have *(insert the reportable disease)* during the study, we will share your name and contact information with the health department.
- <insert if local context requires> State law requires that we tell the authorities if we learn about possible abuse or that you might hurt yourself or someone else.

Where and for how long will my child's information be kept?

- Your child's information given a code and kept <insert local context>
- Once we give your child's information a code, we will keep the key to this code in a <inserted local method for ensure information kept securely, e.g., locked filing cabinet in a locked room>.

- Your child's study information will be stored by the sponsor, ISPCTN DCOC, until the study is completed, including data analysis, and as required by state and federal regulations.
- Only your local study team, the sponsor, and people who audit or monitor for the sponsor will be able to link your child's information to you/your child.
- We < choose "will" or "will not"> put information about your child from the study in your child's medical record.
  - If "will" above then (Describe what information will be put in the participant's medical record.)

If I stop allowing my child to be in the study, what will happen to my child's information collected in the study?

- We will not be able to take your/your child's information out of the study after the study has started.

Will my child's information from the study be used for anything else, including future research?

- If you allow your child to participate in this study, we will keep information from this research study at the ISCPTN DCOC and at the University of Montana. The information may be shared for future research as stated in the NIH (National Institutes of Health) Public Access Policy. This policy makes sure that the public has access to published results of NIH-funded research. The study will also comply with the NIH Data Sharing Policy, Policy on the Dissemination of NIH-Funded Clinical Trial Information, and the Clinical Trials Registration and Results Information Submission rule.

  Information released under this policy will not identify you or your baby or his/her participation in this research study. Other researchers who may see the data may include people who were not part of this study.
- We would also like to keep your address for future use related to this study. One example would be to use your address to link outdoor pollen levels or outdoor air pollution (e.g., from wildfires) to study results. Your address will not be kept with your/your child's health information. You may opt out of this at any time. The signature page has a line for you to let the study team know if we may keep your address for this reason. If you decide later that you do not want the study team to keep your address, you will need to send a written notice to the site investigator named in this consent

Will you tell me the results of the study?

- Air Quality Results:

  In general, your individual home air quality results will not be provided during your child's participation in the study. After your child's participation has ended (after 6 months, or sooner if your child ends participation early), we will put together and send a summary of your individual home air quality results from the study air quality monitors that measure small particles in the air. These results will be sent by your preferred method (such as US postal service). An example of the type of information you will receive is in your study packet.

  Should persistently high air pollutant levels be noticed, you be will be notified either:

  - Early in your child's participation in the BREATHE study (in the first four weeks approximately).
    - Note that this early notification will not be possible if there is a problem with data transmission from the PurpleAir monitors.

    OR

  - After your child completes his/her study participation.
    - At this time, the study team can retrieve air quality readings from the monitors you return and PurpleAir information sent through WiFi (if available).

- Overall Study Results:

  Once the entire study is done for all children, we will provide a summary of the overall study results. These will also be sent by your preferred method.

What if new information comes up about the study?

We will tell you if we learn anything that may change your mind about allowing your child to be in the study.

Where can I find more information about this clinical trial?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website any time.

What if I have questions?

- Please call the principal site investigator <(insert local researcher name> at <insert local phone #> if you

- ✓ have any questions about this study
- ✓ feel your child has been injured in any way by being in this study

- You can also call the office at UAMS that supervises research if you cannot reach the study team, have questions about your child's rights as a research participant, or want to speak to someone not directly involved with this study. To do so, call the UAMS Institutional Review Board at 501-686-5667 during normal work hours (8:00 AM to 4:30 PM, Central time).
- <insert local contact information when applicable>

By signing the document, I am saying:

- ✓ I agree to allow my child to be in the study.
- ✓ I know that joining this study is voluntary.
- ✓ Someone has talked with me about the information in this form and answered all of my questions.
- ✓ I have been asked if I wish to talk directly to the study doctor.

I know that:

- ✓ I can stop allowing my child to be in any and all parts of the study at any time and nothing bad will happen to me or my child.
- ✓ My child can still get medical care at <insert local institution> no matter what I decide.
- ✓ I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my and my child's rights.
- ✓ I do not give up any of my/my child's legal rights by signing this form.

I agree to allow my child to be part of this study:

_____
Printed Name of Parent/LAR* of Participant

_____ _____
Signature of Parent/LAR of Participant Date (mm/dd/yyyy)

**LAR = Legally authorized representative, e.g., legal guardian*

Child's name: _____

Relationship to child: _____

I _____ will _____ will NOT allow the study team to keep my/my child's address for purposes stated in section "Will my child's information from the study be used for anything else, including future research?"

_____ _____
Signature of Parent/LAR of Participant Date (mm/dd/yyyy)

I agree to being contacted for future research related to this study.

___ YES ___ NO

_____ _____
Signature of Parent/LAR of Participant Date (mm/dd/yyyy)

Name/Signature of person obtaining consent:

Printed Name of Person Obtaining Consent	
Signature of Person Obtaining Consent	Date (mm/dd/yyyy)

ATTACHMENT 1

Pictures of Equipment Used in the Study

Figure 1. Air Monitor (PurpleAir)

This measures the amount of very small particles in the air in your home. Also called air quality monitor.

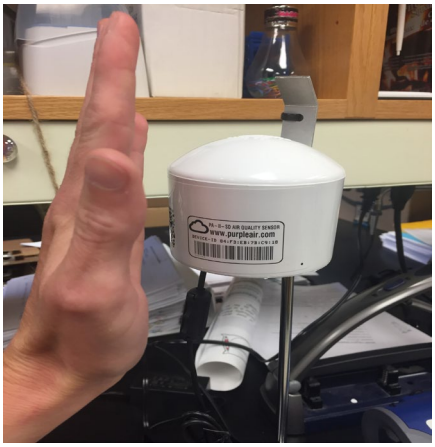

Figure 2. Hotspot

This is needed to let the research team see the information about the amount of particles in the air in your home. It provides WiFi for your PurpleAir monitors.

Figure 3. Air Unit

For those in active group, this will contain the HEPA filter. For those in the control group, this will not have a filter until after you complete the 6 months of data collection. They will look and run the same whether or not there is a filter in it during the 6 months of data collection.

Figure 4. (Kill A Watt Meter)

This will measure the amount of electricity used by the air units. Also called kilowatt meter.