Title: RVA Breathes: A Richmond City Collaboration to Reduce Pediatric Asthma Disparities

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: RVA Breathes

VCU INVESTIGATOR: Robin S. Everhart, PhD, Associate Professor, (804) 828-7249

FUNDER: National Institutes of Health

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study, and to have your child participate as well. **It is important that you carefully think about whether being in this study is right for you, your child, and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation and your child's participation are voluntary. You and your child may decide not to participate in this study. If you and your child do participate, you and your child may withdraw from the study at any time. Your decision and your child's decision not to take part or to withdraw will involve no penalty or loss of benefits to which you and your child are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to determine whether our asthma program, *RVA Breathes*, can help improve your child's daily experiences with their asthma.

What will happen if I participate?

In this study, you and your child will be asked to participate in an asthma intervention program, RVA Breathes, and to complete surveys to help us understand if the intervention is effective. The intervention and research will be conducted over the course of 18 months to two years. First, we will ask you and your child to complete a baseline survey that provides us with information about you and your child's asthma care. Once you complete the survey, you will be randomized (like flipping a coin) into one of 3 groups. Two of the groups will require you to

participate in a minimum of 4 intervention sessions across 9 months to 1 year (you can participate in more if it would be helpful to you and your child). These sessions last no more than 2 hours. The other group is the usual care that your child receives for their asthma; we will also mail you information about asthma 4 times throughout the year. You and your child will complete surveys 3, 6, and 9 months after the program ends. These sessions will last about 45-60 minutes. All sessions will occur at your home. We are hoping that 300 families participate in our research study. The procedures are described in more detail below.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies.

Risks and Discomforts	Benefits to You and Others
• Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you or your child. • The study questionnaires ask questions that are personal in nature and may make you or your child feel uncomfortable. • You may perceive that this study is providing asthma care for your child. This study is not providing asthma care for your child.	This is not a treatment study, and you and your child are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to a better treatment in the future for children with asthma.

Now that you have a general overview of the study, we want to provide the details about what your and your child's participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

WHAT WILL HAPPEN IF MY CHILD AND I PARTICIPATE IN THE STUDY?

The first study visit, **the baseline session**, will last about 90 minutes. You will complete questionnaires about family demographic information, your child's asthma symptoms and control, times that your child has been hospitalized or visited the emergency department because of asthma, the number of days of school that your child has missed due to asthma, information about your child's asthma medications, and questionnaires about managing your

child's asthma, your mood, stress, and quality of life. Your child will report on their asthma symptoms. We will also ask you to provide information related to your child's school and the doctor that your child visits for their asthma. We will also ask you to give us permission to contact your child's school and doctor and receive information from them about the care your child is receiving, including school days missed due to asthma. We will also ask you to give us permission to receive information from your insurance company that will tell us how much visits to the emergency department or hospitalizations cost, and about your child's asthma medications (how many times the prescriptions were refilled and how much the refills cost). Thus, your insurance company will know that you are enrolled in our study, RVA Breathes.

Finally, we will ask you to give us permission to receive information from hospitals that your child has visited because of their asthma. This again is billing information about emergency department and hospitalization costs, as well as information about prescription refills. If your child has been seen at VCUHS, by signing this consent form, you are giving your permission for us to receive that billing information. If your child has been seen at another hospital, we will ask you to sign a separate release form.

To be clear, we are asking for your permission to talk to several different people about your child's asthma. These people (i.e., school nurse, primary care doctor) will also be communicating directly with each other about your child's asthma. This will be done to try to ensure that your child is receiving coordinated care or care for their asthma from multiple people that fits well together.

Randomization. After you complete the baseline research session, you will be randomly assigned to one of 3 groups. Random assignment is like flipping a coin to see which group you will participate in.

Group 1: School + Asthma education + Home triggers

A few weeks after the baseline session, a community health worker (CHW) and a person from the Healthy Homes Program will visit you and your child in your home. You will receive family-based asthma education and you will also complete a home assessment. A home assessment can sound a little overwhelming! It is important to know that we are trying to better understand how to make simple adjustments in your home to help your child with asthma feel better. The person from Healthy Homes will look at both the interior and exterior of your home and look at things such as standing water, mold, pests, and other aspects of the home environment that could make your child's asthma worse. This home session will last about 2 hours and both you and your child will be present. At the session, you will answer questions about your child's asthma, learn more about your child's asthma from materials (e.g., binders, handouts) that we will bring with us, and walk through your home with the person from Healthy Homes.

After that first intervention session, CHWs will work with our research team to determine the best way to coordinate your child's care and participation in the program. This will also mean reaching out to your child's primary asthma doctor to update them on your family's

participation in the intervention. We will send your child's primary asthma doctor a summary of each session that tells the doctor broadly what information was covered in the session. Information from any visits your child has with their primary asthma doctor may also be communicated back to us. Again, it is important to know that this information is being shared with your permission to ensure that doctors and your CHW are on the same page about your child's asthma. In the same way, we will also talk to your child's school nurse to make sure that they have the forms and medication that they need to be sure your child's asthma is well taken care of at school. If you are in Group 1, your child's school nurse will know that your child is participating in our program, *RVA Breathes.* Your child's school nurse will have asthma-specific instructions to follow if they see your child in school because of their asthma. School nurses will also let your CHW know if they treat your child at school. Again, the big picture idea behind our study is to make sure that the care your child receives for their asthma is communicated between you, the school, your child's doctor, and your CHW.

Two to three months later, the CHW and the Healthy Homes person will return to your home to educate you more about asthma and provide more ways to make practical changes to your home. Two to three months after that session, Session 3 will occur, and finally, 2 to 3 months later, Session 4 will occur. At each session, you will learn more about asthma and work more on improving the home environment to reduce asthma triggers. It is important to note, however, that your CHW may determine that more frequent home visits or phone calls in between the main 4 sessions are needed. Your child's school nurse will continue to receive education about asthma; your child's asthma doctor, school nurse, and CHW will continue to communicate about your child's asthma to ensure that everyone is doing the best they can to improve your child's asthma.

In sum, if you are assigned to Group 1 of *RVA Breathes*, you will complete a minimum of 4 home sessions that occur every 2-3 months across 18 months to 1 year.

Group 2: Asthma education + Home triggers

This group is similar to Group 1, only there is no involvement with your child's school nurse. Participants in this group will complete the same minimum number of home sessions as Group 1. These four sessions again include a home visit from a CHW and a person from the Healthy Homes Program. They will last 2 hours and will occur every 2-3 months. The care management team will still work with your CHW and child's asthma doctor to coordinate your child's asthma care, but will not communicate with your child's school nurse.

Group 3: Usual Care

If you are randomized to Group 3, you will continue to work with your child on his or asthma in whatever way you typically do. In addition, we will mail you publicly-available information on asthma every 2-3 months during the first year of your participation. This means that this information is already published and available on the Internet from sites such as the American Lung Association, or Centers for Disease Control. Our project coordinator will mail this information to you. Someone from our team will also call you around the same time that we mail these materials to you. We will check in with you about whether your child has been to the

hospital or emergency room for asthma since the last time we spoke with you. If you tell us that your child has, then we will follow up and ask you which hospital your child went to and if you know the date that they went to that hospital. In this group, you will still participate in all baseline and follow-up research sessions; there are 5 in total.

All Groups: Follow-up sessions
After the first 9 to 12 months of your participation in RVA Breathes, we will schedule 4 more home visits to see how things are going since you were a part of our program. Two research assistants will visit your home to conduct these visits.

Follow-up Session #1: The first follow up session will occur about 2 weeks after the program ends and last 60 minutes. At that visit, you will complete the same questionnaires that you did at our baseline session. We will also ask you and your child some questions in a short interview. We will ask you to describe how the program met or did not meet your expectations, and what you liked or didn't like about the program.

Follow-up Sessions #2-4: These sessions will last about 45 minutes and occur in Months 3, 6, and 9 in Year 2. You will complete the same questionnaires as you did at the first follow-up session.

WHAT RISKS AND DISCOMFORTS COULD MY CHILD AND I EXPERIENCE FROM BEING IN THE STUDY?

Non-Physical Risks
Perceived risks for participating in this study are minimal. You or your child may find some of the questionnaires upsetting or may be uncomfortable answering questions about your mood or ability to manage your child's asthma. You and your child can choose not to answer any questions and can stop participating in the study at any time without penalty. The research team will be glad to refer you to outside counseling services in the rare case of extreme distress.

Breach in confidentiality is another potential risk, however safeguards will be in place to deter this possibility. Paper-based records will be kept in a secure location and accessed only by authorized study personnel. Electronic records will be made available only to those personnel in the study through the use of access controls and password-protected files. Personal identifying information will be removed from study-related data and data will be coded. A Data and Safety Monitoring Board will be in place to ensure the safety of subjects. This just means that there is a group of researchers that will make sure Dr. Everhart and her team are doing everything they can to keep your information protected.

Another risk is that you may perceive that this study is providing asthma care for your child. This study is not providing asthma care for your child. The CHWs or other research personnel are not your child's medical doctors. This study is not a substitute for the typical medical care

that your child receives; we will not be giving you medical advice like your doctor. Visits during this research study are conducted by research staff and should not take the place of visits to your usual healthcare providers. During your participation in RVA Breathes, you should keep appointments with your child's doctor and contact your doctor with your asthma questions.

Finally, there is the potential risk of retaliation from landlords should you express concerns about your living conditions to your landlord. We want to assure you that Healthy Homes will not communicate anything with your landlord without your consent. Healthy Homes will make sure that you know your rights as a tenant, and what the potential outcomes of sharing findings from the Healthy Homes assessment with your landlord might be.

Unknown or Unforeseeable Risks

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

At the baseline session, you will receive $30 for your time and your child will receive a small prize, such as a notepad, pencil, or small toy. We will ask you to approve the prize before we give it to your child. If you are in the intervention group, you will receive $20 at the second and at the third intervention sessions. You will receive $40 for completing the first follow-up session that occurs in Year 2 (after you have been in RVA Breathes for 9 to 12 months), $60 for the 3-month follow up session (Follow-up Session #2), $70 for the 6-month follow up session (Follow-up Session #3), and $100 for the 9-month follow up session (Follow-up Session #4). Families in the intervention group can receive up to $340 total for participation in this project. If you are in the control group, you will receive $50 for completing the first follow-up session in Year 2, $70 for the 3-month follow up session, $80 for the 6-month follow up session, and $100 for the 9 month follow up. Families in the control group can receive up to $330 total for participation in this project. You will receive all payments at the end of the sessions; payments during intervention session 2 and 3 will be in the form of $20 gift cards sent to your email. Children will receive small prizes at each of these sessions that you have approved.

You may be asked to provide your social security number in order to receive payment for your participation. Your social security number is required by federal law. It will not be included in any information collected about you for this research. Your social security number will be kept confidential and will only be used in order to process payment.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

CAN MY CHILD OR I STOP BEING IN THE STUDY?

You or your child can stop being in this research study at any time. Leaving the study will not affect your or your child's medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.
Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your or your child's health or safety
- you or your child are found to not be eligible for the study
- the sponsor has stopped the study
- you or your child have not followed study instructions
- administrative reasons require your or your child's withdrawal

If you leave the study before the final scheduled visit, nothing bad will happen to you or your child. We will ask that you provide a final opportunity for us to meet with you and your child to collect a final set of questionnaires from you.

HOW WILL INFORMATION ABOUT ME AND MY CHILD BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your and your child's information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

In general, we will not give you any individual results from the study.

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

We will not tell anyone the answers your child gives us. However, if your child tells us that someone is hurting her or him, or that she might hurt herself or someone else, the law says that we must let people in authority know so they can protect your child.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. This certificate offers the protections described here. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers may share information about you or your participation, or your child or your child's participation, in the research project without your consent if there is child or elder abuse or neglect, or harm to self or others.

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

HOW WILL MY OR MY CHILD'S HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your child's healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or

questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

☒ Complete health record	☒ Diagnosis & treatment codes	☐ Discharge summary
☐ History and physical exam	☐ Consultation reports	☐ Progress notes
☐ Laboratory test results	☐ X-ray reports	☐ X-ray films / images
☐ Photographs, videotapes	☒ Complete billing record	☐ Itemized bill
☐ Information about drug or alcohol abuse		☐ Information about Hepatitis B or C tests
☐ Information about mental health		☐ Information about sexually transmitted diseases
☐ Other physical or mental health information (specify):		

Who will use or share protected health information about me?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
- Study Funder
- Data Coordinators
- Research Collaborators
- Data Safety Monitoring Boards

Once your or your child's health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at Robin S. Everhart, PhD, Box 842018, Richmond, VA 23284.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Robin S. Everhart, PhD, (804) 828-7249, reverhart@vcu.edu
and/or
Devon Withers, (804) 828-6093, withersda@vcu.edu

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT AND PARENT/LEGAL GUARDIAN PERMISSION

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I and my child otherwise would be entitled. My signature indicates that I freely consent to participate [and give permission for my child to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Signature Block for Enrolling Child Participants - Parent/Guardian Permission
_____ Name of Child/Youth Participant
_____ Name of First Parent/Legal Guardian (Printed) *Study team – verify that this individual is the child's parent or legal guardian.*

_____	_____
Required First Parent/Legal Guardian Signature	Date
_____	_____
Optional Second Parent /Legal Guardian's Signature	Date
_____	
Name of Person Conducting Parental Permission Discussion (Printed)	
_____	_____
Signature of Person Conducting Parental Permission Discussion	Date
_____	_____
Principal Investigator Signature (if different from above)	Date

Signature Block for Enrolling Child Participants (Ages 7-17) – Assent by Child

STATEMENT OF ASSENT BY CHILD PARTICIPANT

The person doing this research study has explained what will happen to me if I participate in this study. My signature below means that I want to be in this study. I can decide not to be in this study if I do not want to. Nothing will happen to me if I do not want to participate.

_____	_____
Child Participant's Signature	Date
_____	
Name of Person Conducting Assent Discussion (Printed)	
_____	_____
Signature of Person Assent Discussion	Date
_____	_____
Principal Investigator Signature (if different from above)	Date