STRONG MEMORIAL HOSPITAL
SCHOOL OF MEDICINE AND DENTISTRY
SCHOOL OF NURSING
DIVISION OF PULMONARY AND CRITICAL CARE MEDICINE
DEPARTMENT OF PUBLIC HEALTH SCIENCES

CLEAN AIR TO REDUCE EXACERBATIONS (CARE) STUDY

Informed Consent Form

Principal Investigator: Daniel Croft MD, MPH

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate.

- Being in this clinical trial is voluntary – it is your choice.
- You are being asked to take part in this study because you have chronic obstructive pulmonary disease (COPD).
- The purpose of this study is determine if indoor air cleaning can improve your quality of life, decrease inflammation in your body and reduce your risk for COPD exacerbations.
- Your participation in this study will last for about 8 months (31 weeks).
- Procedures will include installing a high-efficiency particulate arrestance (HEPA) filter unit (similar to a window mounted air conditioning unit) in the windows of your bedroom and living room.
- We will also draw blood, and measuring your daily activity with a smart watch, which will sync to a smartphone.
- There are risks from participating.
    - The most common risk is discomfort from blood draws.
    - One of the most serious risks is loss of privacy. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- You might not benefit from being in this research study. The potential benefit to you might be that the improved air quality in your home temporarily makes you feel better.
- You will be compensated for your time, electricity use, and travel for blood draws.
- If you do not want to take part in this study, continuing your current treatment plan would be appropriate.

RSRB Approval Date: 9/19/2019
Expiration Date: 9/18/2020

Introduction and Purpose of the Study
Indoor air pollution consists of particles (e.g. dust) and gasses (e.g. cooking) that come from indoor sources, or from outside air coming into the home. Indoor air pollution can irritate the lungs and make it harder for you to breathe. It can also cause whole body inflammation and lead to exacerbations (worsening of your symptoms) of chronic obstructive pulmonary disease (COPD) leading to hospitalizations. You are being asked to participate in this research study because you have COPD and have suffered an exacerbation of COPD in the past year.

This study looks at whether air cleaning devices put in the bedroom and living room of your home could reduce the irritation of your lungs and body that is caused by indoor air pollution. While participating in this study there will be two, 8 week long study segments (Study Period 1 and Study Period 2) where the air filter units, placed in your living room and bedroom windows, will be turned on at your home.

This clinical trial will have an intervention period and a placebo period. During the 8 weeks intervention period the unit will heat/cool and clean the air. During the placebo period, the unit will only heat/cool the air but not clean the air. A placebo period is essential to a clinical trial as it helps us determine if the changes observed in the study are related to the intervention (the air cleaners in this case), or to random chance.

HEPAirX® Air cleaning device
We will be using two HEPAirX® air filtration devices to clean the air in the bedroom and living room of your home. These devices are approved by the U.S. Food and Drug Administration (FDA) for this use. One air filter will be installed in one of your bedroom windows and another will be installed in a living room window. These devices are a little larger than a standard window air conditioning units and have the following dimensions (22 inches wide by 22 inches high by 29 inches deep). They still fit in a standard double hung window. These devices will be set to run for 8 weeks during Study Period 1 and another 8 weeks during Study Period 2. There will be a 3-week break between the two Study Periods, when the air filters stay in your windows, but are turned off. The HEPAirX® device fits into a window as a slightly oversized window air conditioner unit, operates on normal electric power, and provides the heating or cooling required to maintain a constant room temperature. We will show you how to change the temperature on the unit. The unit filters and ventilates the air to remove pollution coming from inside and outside the home, from your bedroom.

For each of the two 8-week long Study Periods, you will have the devices in your bedroom and living room, and they will need to stay turned on the entire time. For one Study Period (8 weeks), the device will filter and ventilate the air to remove indoor and outdoor generated pollution (filtration mode). For the other period (8 weeks) weeks, the device will look and sound the same, but will not be filtering or ventilating the air to remove the pollution (neutral mode). We will randomly assign you to either have 8 weeks of filtering followed by 8 weeks of non-filtering or 8 weeks of non-filtering followed by 8 weeks of filtering. Our study staff will install and take the device out of your home at the end of the second Study Period (week 19). Neither you, nor the study team, will know the ordering of filtering/non-filtering by the air cleaning device.

Before and after each of these Study Periods, we will measure the amount of inflammation you may have in your blood, and ask you questions about your quality of life using a standard questionnaire used for people with COPD. We will also be measuring the air quality in your home during the study and monitoring how active you are during the Study Periods.

Study Description

Procedures:
If you choose to participate the following things will happen during the course of the study:

- We will go over this consent form with you and answer any questions you may have about the study.
- You will be provided with the following items for use during the study:
    - A FitBit® (step counter worn on the wrist) that you will be asked to wear during the day to track how active you are and will also track your heart rate.
    - You will be responsible for charging this Fitbit every 4 days (charger included)
    - We will provide you with a smartphone to use to sync the Fitbit data when you charge the Fitbit every 4 days. This phone will also requiring charging every 4 days.
    - Five air quality monitors (about the size of a small tabletop alarm clock) that you will be asked to place in your home.
    - One of our research members will come to your home to install HEPAirX® air filters in the bedroom window and living room window of your home.
- You will need to travel to a Strong Memorial Hospital lab) to have a total of 4 blood tests over the course of this study (at the beginning and end of each Period) to monitor your C reactive protein (CRP), a measurement of inflammation in your blood. Each blood draw will take about 2 teaspoons (10mL) of blood. These blood tests will be paid for by the study.
    - In addition to the 5ml of blood drawn for the CRP test, 5ml of additional blood will be stored for future research involving the effects of indoor air cleaning
    - During these visits you will also be asked to perform a 6 minute walk test while wearing your Fit Bit.
- During the two, 8 week Study Periods, you will be asked to keep an activity diary to note when activities that can affect air quality are occurring (such as cooking or cleaning) or when you leave the main living area to go to your bedroom.
- We will visit your home a total of 4 times during the study. These visits will be scheduled at a time convenient for you at the start and stop of Study Period 1 and the start and stop of Study Period 2. These visits should last about 1 hour. The study periods are explained below. We will also call you midway through Study Period 1 and 2 and may need to visit your home to check on the equipment.
- We will also have you complete the St. George's Respiratory Questionnaire (SGRQ) regarding your functional status and quality of life at 5 time points throughout the study.
- The research staff will monitor your medical records to see when or how often you are treated for a COPD exacerbation while you are on study.

Getting started:
If you agree to participate after reviewing this consent form the following will be done within the first two weeks:

- We will provide you with a FitBit® for use during the study. This is a device worn on your wrist, similar to a wrist watch, that will track how many steps you take (how active you are) each day. It also measures heart rate, which may be used in a future study but is not a planned outcome of this study. You will be shown how to use the FitBit® and asked to wear this tracker each day at least during waking hours but you are welcome to wear this at night also if you wish. On average, it will need to be charged every 4 days (charger provided).
- We will provide you with a smartphone to use for syncing the Fitbit device (every 4 days when you charge the Fitbit). We will provide directions on how to do this.
- We will provide you with multiple in-home air quality monitors to take home (to measure particles and gases. These devices will be monitoring the quality of the air in your home for the duration of the study. You will be asked to plug them into an outlet in your living room in a location that is not a 'high traffic area' where people will be walking by it very frequently.
- You will be asked to have a CRP blood test (about 1 teaspoon of blood) at the University of Rochester laboratorie. This will measure how much inflammation is in your blood currently.
- You will be asked to complete a 6 minute walk test when at the University of Rochester laboratory.
- You will be asked to complete the SGRQ (questionnaire)
- A time will be scheduled with you to have a study member come to your home to install the 2 HEPAirX® air filters in the widows of your living room and bedroom of your home. You will be shown how to adjust the air temperature of the units for your comfort. The units will be turned on at this visit and you will begin Study Period 1.

Study Period 1 (8 weeks long):
The HEPAirX® air filters will be turned on. Neither you nor the study doctor will know if the units are in Filter Mode or Neutral Mode during this Study Period.

- You will be asked to have a repeat CRP blood test and 6 minute walk test after the units have been working for 8 weeks at your home.
- You will be asked to track activities and illness as they arise that may impact the air quality of your home on an activity/illness diary. Specifically for illness you would track when you feel ill or experience infectious symptoms (i.e. worsened sinus congestion, runny nose, cough or increased sputum production) The research staff member will explain to you which activities to track and how to track them.
- We will check in with you by phone 1 month into this period to ensure all your questions are answered and will let you know if we need to check on any equipment in your home.

Washout Period (3 weeks long):
After the units have been running for 8 weeks, a research staff member will come to your home to turn off the units. During that visit the following things will happen:

- The researcher will download the information from Study Period 1 on your FitBit tracker into the study database, and
- Your activity diary will be collected, and
- You will be asked to complete the SGRQ, and
- You will also be asked to go to the lab for a repeat CRP blood test and walk test.

Study Period 2 (8 weeks long):
The research staff member will return to your home to turn on the HEPAirX® air filters once again. If your units were set to Filter Mode the first time, they will now be switched to Neutral Mode. If they were in Neutral Mode the first time, they will now be switched to Filter Mode. Neither you nor the study doctor will know if the units are in Filter Mode or Neutral Mode during this Study Period. During that visit, the following things will happen:

- The researcher will download the information from the washout Period on your FitBit® tracker into the study database, and
- You will be asked to complete the SGRQ, and
- You will be asked to track your activities on an activity diary.
- The units are activated at your home.
- We will check in with you by phone 1 month into this period to ensure all your questions are answered and will let you know if we need to check on any equipment in your home.

End of Study Periods:
After the units have been running for this second 8 week period, a research staff member will come to your home to turn off the units and take them out of your home. During that visit the following things will happen:

- The researcher will download the information from Study Period 2 on your FitBit® tracker into the study database, and
- Your activity diary will be collected, and
- You will be asked to complete the SGRQ, and
- You will be asked to have a repeat CRP blood test and 6 minute walk.
- The FitBit® tracker, smartphone and air quality monitor will also be collected.

3 Month Follow-Up:
Approximately 12 weeks (3 months) after you finish Study Period 2, a research staff member will contact you to repeat the SGRQ one last time. We will also ask if you have suffered from

any COPD exacerbations over that period. After the last questionnaire is completed, your study participation is over.

Home Visits
Please be aware that researchers are required to report information regarding potential child abuse or neglect reported by you or observed at your home during the research visit. The researcher will also report if there is a reasonable suspicion, based on information provided by you or observed during the research visit at your home, that you may present a danger of harm to others or that you may harm yourself unless protective measures are taken.

Number of Subjects
We plan to enroll 20 subjects over approximately 1 year.

Duration of the Study
If you decide to participate in this study, your participation will last approximately 31-33 weeks (about 8 months) from the time you give consent to participate until your follow-up is complete.

Future participation in a community program:
If you agree, we will give your name and contact information to our partners in the Environmental Health Sciences Center (EHSC) who will contact you about healthy home information and resources. These resources would be related to the Rochester Healthy Homes Partnership, a group of researchers and community members. This is optional and we will only share your contact information with EHSC if you provide consent to do so.

"The Rochester Healthy Homes Partnership supports local efforts to reduce home environmental health hazards throughout our community, particularly for children and low-income residents of the City of Rochester. In recent years, the RHHP has focused on promoting healthy homes outreach. The RHHP has met approximately monthly since 2009 and maintains a listserv to share resources, coordinate activities, and collaborate on new projects."
https://www.urmc.rochester.edu/environmental-health-sciences/coec/projects-partnerships/healthy-homes/rochester-healthy-homes-partnership.aspx

Description of Genetic Testing Study Procedures (that may be performed on stored samples)
Sometimes tissue and blood are used for genetic research about diseases that are passed on in families. If you do not understand what a genetic test is and wish to receive additional counseling from a genetics professional prior to signing this consent, please let us know.

Future Genetic Testing: We may run tests on the extra 5ml of blood collected to investigate if something related to your underlying genetic code has made you more or less susceptible to indoor air pollution related disease. If you allow us to use your samples, they will be kept indefinitely, as long as they are useful for research. Records about you and the genetic testing will be kept in a coded fashion by the principal investigator, the co-principal investigator and the study coordinator in a secure password protected database or in a locked filing cabinet.

You are free to decide if you wish to participate in the genetic testing portion of the study. If you decide to participate in this portion of the study, you will be asked to sign this consent form, specific to the genetic testing, detailing the risks of donating a sample for genetic testing.

Though we will provide feedback on your results of the indoor air cleaning study after its conclusion, you will not receive the results of the genetic research done with your specimens. This is because research can take a long time and must use specimen samples from many people before the results are known. Results from research performed using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future. We do not expect to discover any information of direct clinical relevance to your condition in the next few years.

If you decide that you don't want to be in the study any more, let us know and we will remove you from the data; however, any samples and data that have been de-identified cannot be destroyed.

Handling of Samples

All blood samples designated for genomic DNA will be kept in the lab securely indefinitely and may be used for future research. Your identity will be unknown by the laboratory staff, but samples will be coded so that the study coordinators can correlate your diagnosis to any potential factors found by the studies done on your donated samples in the laboratory. The filters from your indoor air cleaner will be saved and the particles/dust extracted from this may be used in a future study to help determine what specific types of particles were present.

Risk of Participation

Risks:

Blood collection

Blood draws may cause pain, redness, bruising or infection at the site of the needle stick. Rarely some people faint.

Wearable FitBit® Sensor

The band that wraps around your wrist may cause irritation on your arm (though this is unlikely). Please notify the study team if you notice any rash or skin irritation in the area of your FitBit® monitor. We will also check the skin on your wrist for irritation during your home visits.

Energy consumption

We have calculated the amount of energy that the units are expected to use with average heating temperatures of 68-75 and cooling temperatures of 70-75 and have provided compensation for this. Even at these normal operating temperatures if there is an increase in your energy bill larger than you are compensated for, please bring this to our attention and we will ensure an equitable solution. However, if the machines are used at the extremes of temperature ranges (heating to 80 degrees in the winter or 60 degrees in the summer), the energy bill will likely exceed what we have provided and we will determine additional compensation on a case by case basis.

Quality of Life Questionnaire (SGRQ)
It may be uncomfortable for you to answer personal or difficult questions about your COPD and how it affects your activities of daily living. You can skip any of the questions you do not want to answer and you can stop at any time.

Loss of Privacy
Loss of privacy is a potential risk if the information collected were to be released. However, this risk is minimized by using a code number and removing information that may directly identify you, such as your name or medical record number. However, certain identifiers, such as dates and times related to hospital admissions and/or other respiratory events noted on your diary and corresponding dates and times of air pollution measurements and activity data on the FitBit devices will be maintained and possibly used as part of future research. Any information collected will be kept in a safe, secure, password protected computer and access to this information will be limited to only approved research staff.

AirViz Inc. is a company providing us with some of the air quality monitors used in this study. Once all the air quality monitors are collected from your home, they will be sent to AirViz to remove the data from the monitors. AirViz, Inc. will review the data collected from the monitors to ensure data quality. The data will then be sent to us for use in our research analysis. AirViz Inc. will not receive any personal health information or other information that could identify you.

Also there is a risk to loss of privacy given our entry into your home, living room and bedroom for installation of the indoor air cleaners. This risk of loss of privacy will be minimized by our calling to announce any home visit and not discussing anything regarding your home not relevant to air study (factors that impact air quality).

Benefits of Participation
You will not benefit from being in this research study.

Costs and Payment
There is no cost to you to participate in this research study.

The CRP blood test will be paid for by the study. You will be paid up to $580.00 if you complete all study activities. The breakdown of the payments is as follows:

1. Driving to the lab for blood draws: $20 per lab visit x 4 visits = $80. Valet parking will be arranged and paid for at each visit.
2. Compensation for scheduled home visits: $25 per home visit x 4 visits = $100
3. Compensation for energy costs: $200 per Study period x 2 periods = $400

We will pay you these amounts in the form of a check. These checks will be given to you in the following amounts at the 4 home visits:

- Home Visit 1: $45.00 ($25 Home Visit #1 + $20 blood draw #1)

- Home Visit 2: $245.00 ($200 Study Period 1 electricity costs + $25 Home Visit #2, + 20 for blood draws #2)
- Home Visit 3: $45.00 ($25 Home Visit #3 +$20 blood draw #3)
- Home Visit 4: $245.00 ($200 Study Period 2 electricity costs, $25 Home visit #4 + $20 for blood draws #4)

Total = $580

Sponsor Support
The University of Rochester is supporting this research.

Air Innovations, the maker of HEPAirX® is supplying the air filtration units for use on this research study at no cost but will not be involved in any other portion of this study.

AirViz, Inc. is providing us with discounted access to some of the air quality monitors used in the study. They will remove the data collected from the monitors and perform a data quality review before sending the data on to us for the research analysis. They will not be involved in any other portion of this study.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes
The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will limit access to research data to only approved research staff members. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of thisresearch
- Records about your study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Results of medical tests (blood tests)

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- AirViz, Inc.

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

- Then you will not be able to be in this research study.

May I review or copy my information?

- Yes, but only after the research is over.

How long will this permission be valid?

- This permission will last indefinitely.

May I cancel my permission to use and disclose information?

- Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?

- Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

- No. There is a risk that your information will be given to others without your permission.

New information

If we discover any new information that might make you change your mind about continuing in the study, we will let you know.

Voluntary Participation
Participation in this study is voluntary. You are free not to participate and can withdraw yourself at any time, for any reason. If you do not choose to participate, or you choose to withdraw from the study, it will not put in jeopardy any relationships that you have with the faculty at the University of Rochester or Strong Memorial Hospital. In the event that you do withdraw from this study, the information already provided will be kept in a confidential manner. You can also join the study even if you choose not to consent to your blood being stored for future studies.

Contact Persons
If at any time you have a question about the study, you may feel free to contact the Principal Investigator, Daniel Croft at 585-273-3860. If there are technical issues or malfunction with the HEPAirX device please turn the device off and contact our team during business hours (8a-5pm) during the weekdays.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642-8315, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Subject Consent
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I will receive a signed copy of this form for my records and future reference.

Please Check Appropriate Response:

Storage of unused blood:

1. _____ I agree to have my blood samples drawn and used for future research.
   _____ I do not agree to have my blood samples drawn and used for future research.

Future contact by the Rochester Healthy Homes Partnership following conclusion of this study

2. ____I agree to be contacted by the Environmental Health Sciences Center (EHSC).
   ____I do not agree to be contacted by the EHSC

Study Subject: _____
Print Name

Study Subject: _____ _____
Signature Date

Person Obtaining Consent
I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date