Reducing Particulate Matter-associated Cardiovascular Health Effects for Seniors (RAPIDS2-Ypsi)

NCT04103346

Date or IRB Approval: September 12, 2024

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INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
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NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**: Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

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DO NOT upload a clean version of the consent**.**

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UNIVERSITY OF MICHIGAN CONSENT TO BE

PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

Reducing particulate matter-associated cardiovascular health effects for seniors. (RAPIDS2-Ypsi).

Company or agency sponsoring the study:

The National Institute of Health is funding a collaboration between Michigan State University and The University of Michigan. Michigan State University will be responsible for collecting the environmental information such as the pollution contents of the filters placed in your apartment.

Names, degrees, and affiliations of the principal investigator and study coordinator:

Principal Investigator: Geoffrey Barnes, M.D. Assistant Professor of Medicine, Division of Cardiovascular Medicine, University of Michigan.

Research Associate: Robert Bard, MS. Division of Cardiovascular Medicine, University of Michigan.

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, risks are discussed in section 5.1 and are associated with the blood pressure measurement. These risks may include, numbness/tingling, and bruising of the arm.

This study may offer some benefit to you now or others in the future by learning how to decrease your exposure to air pollution which can improve an individual's or the general public's health. This study may not offer any benefit to you now but may benefit others in the future by providing valuable information that leads to other studies that can improve public health. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about 10 weeks: 4 weeks of air filtration plus a one or two week break between each condition. Details are in section 4.2.

You can decide not to be in this study. Participating or not participating in this study will not influence your living situation at Carpenter Place.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

To determine whether air purifiers are capable of lowering the indoor air pollution of your apartment and whether those changes will improve your blood pressure. This is important because air pollution is associated with cardiovascular risk and increased blood pressure.

A recent study improved blood pressure with air filtration for 3 days and now we are investigating a longer study period.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished there will be no penalty to you and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You may participate if:

- Residents of Carpenter Place Apartments who are at least 60 years old.
- Participants may not smoke, live with someone who smokes or have daily exposure to second-hand smoke.
- You must sleep at your home during your active participation in the 10-week study.

Some health conditions that may prevent you from participating. The investigators will determine if your health history will affect the study results and you may be excluded if you:

- Have had a cardiovascular health event in the past 3 months (such as: heart attack, stroke, heart failure, bypass surgery, angina or chest pains).
- Have lung disease requiring oxygen.
- Undergoing renal dialysis.
- Currently receiving cancer treatment.
- Have severe uncontrolled blood pressure ≥160/100 mm Hg or a low systolic blood pressure less than 115 mm Hg.
- Have a recent history of high blood glucose blood glucose ≥220 mg/dl.
- Anticipate changes in your medications during the study.
- You have a condition deemed by the investigators that may interfere with the study interpretation or your ability to participate in the study.

3.2 How many people are expected to take part in this study?

We hope to have 50 people complete the study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

All visits will occur at Carpenter Place. For visits that occur outside your home, a private room will be used within the apartment complex. This same room will be used for all study visits.

Consent Subtitle: _____

Consent Version: _____

We will place an air purifier in your home for 2 different 4-week "blocks". The purifiers will be removed between each block. One block the purifier will be inactive (no filter inside them), one block the filter will be active. The order is random and you will not know when filters are active or inactive.

Screening Visit: We will discuss the study responsibilities and review your medical history to determine if you are healthy enough to participate.

Health Studies: The tests described below are performed during each block.

- **Daily** (M-F Weeks 1,4,7,10) **Home Blood Pressure Measurement:** each morning and evening before bed and upon waking up you will take your blood pressure with a home device we supply. Do not take your blood pressure medications before your morning blood pressure measurements; you may take the medications that may influence your blood pressure after taking your blood pressure.
- .
- **Personal Air Collector**: You will keep this monitor with you everywhere you go for 24 hours between Thursday and Fridayat week 4. The personal air collector (PDR-1500) is a portable device (about 7 inches by 6 inches)) that contains a filter that allows us to analyze the air you are exposed to.
- **Air Filters:** Weeks 2-3 and 7-8: You will not have any visits or studies performed but the air purifier will keep running in your home and you will continue to sleep in your own apartment. The first and last 4 week blocks will be the same, the only difference is the filters will have the opposite condition (active vs. inactive filtration) and you will not know the condition.
    - The filtration device is the Holmes HAP8650B-NU-1 system. One of the study team members will deliver the devices to Carpenter Place and instruct you to place them in your bedroom. Due to Covid, we will only enter your apartment if you need assistance with the equipment and will sanitize any equipment that enters or leaves your apartment. The filtration devices will be kept in your apartment for 4 weeks under each of the 2 different blocks. These devices are 23.9 inches high x 21.7 inches wide x 11.3 inches deep. These devices make a constant background noise, like a 'shhhhh'. Some people may find the nois e bothersome at first, but quickly get used to it.
    - **Activity Diary:** You will be asked to document your movements during the study blocks. This includes the amount of time spent in-doors, outside, etc.

If your medications change during the time you are in the study, please inform the study team.

Weeks 6-9: Repeat the activities of Weeks 1-4. **Study Break** Week 5 and 6 you are free to travel away from your apartment.

Subject Responsibilities: As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you pick-up and return equipment used for the study, and reporting any adverse reactions.

4.2 How much of my time will be needed to take part in this study?

The entire study will take 10 weeks: 4 weeks of air filtration under 2 different conditions plus a 2 week break between each condition. The screening visit will take approximately 30-60 minutes as we explain the study, discuss your medical history, determine smoking status, and sign this consent form. Daily home blood pressure monitoring will take about 15 minutes each day.

4.3 When will my participation in the study be over?

Your participation is for 10 weeks.

Consent Subtitle: _____

Consent Version: _____

4.4 What will happen with my information and/or biospecimens used in this study?

Your collected information may be shared with the sponsor listed in section 1.

With appropriate permissions, your samples and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are: a risk of a loss of privacy because others may see you coming/going with study materials and determine that you are participating in the air filtration study. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

The most common side effects (occurring in more than 10% of patients) are:

- Pain, numbness/tingling, and bruising of the arm may occur with blood pressure monitoring.

The researchers will try to minimize these risks by being discrete when discussing the study with you and not sharing any information with others regarding your participation. Experienced study team members will complete other study related activities.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

You may choose not to participate in this study if you choose. Participating or not participating in this study does will not influence your living situation at Carpenter Place.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

You are unlikely to experience any harm. If you decide to leave the study, you will be required to return the study equipment to the study team.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will be paid $400 for your participation in the study. Partial payments will be pro-rated at $200 per block completed. We will mail you a check at the end of your participation. If you do not complete a complete block of 4 weeks, you WILL NOT be paid.

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the sponsor which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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 Web site will include a summary of the results. You can search this Web site at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results and dental records.
- All records relating to your condition, the treatment you have received, and your response to the treatment

- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared

with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments ☐☐Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Geoffrey Barnes, MD
Study Coordinator: Robert Bard
Mailing Address: 24 Frank Lloyd Wright Drive Lobby A, Ann Arbor, MI 48108
Telephone: 734-998-4939 email: bbard@umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234 e-mail:
irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

You will receive a copy of the signed and dated informed consent.

Your signature in the next section means that you have received copies of all of the following documents:

☐☐This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*

Consent Subtitle: _____

Consent Version: _____

12. SIGNATURES

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____