NYU Langone Health

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NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	Cardiometabolic biomarker improvements associated with reduction in air pollution exposure via home air filtration. s22-00045
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to investigate if reducing air pollution exposure using portable air cleaners can change the amount of inflammation in the blood, in people with high blood pressure. In this study, we will investigate the relationships between pollution and inflammation using blood tests. These markers of inflammation have been shown to relate to cardiometabolic risk. We will also investigate the relationship between changes in these proteins and blood pressure. You are invited to participate because you have high blood pressure.

3. How long will I be in the study? How many other people will be in the study?

You will be involved in the study for about 5 weeks and have 3 study-related visits (two in person, one by video). The whole study will last about 1 year.

We expect to have about 75 people in the study.

4. What will I be asked to do in the study?

Before any research procedures are done, you will be asked to read and sign this consent form. If you agree to participate in this study, the following will happen:

1. **Baseline Visit:** We will review your medical records for the following information:

- clinical history
- demographic information (age, gender, etc.)
- Height, weight, waist circumference and blood pressure
- medication use

We will ask you a series of questions to make sure you are eligible to undergo blood draw and are able to take part in the study. If you are eligible, the blood draw will be done by qualified study personnel and will take place either at your doctor's office or another private clinical space at NYU.

Baseline Blood Draw: No more than 15 ml (≈1 tablespoons and 3% of a standard blood donation) of blood will be collected and stored in tubes. This blood will be used to collect labs that are related to risk of heart disease, including measures of inflammation. If you opt-in to give samples for future research, we will draw an additional ~10 mL of blood at the same time. These samples will be stored for future studies that may include genetic research related to inflammation and other risk factors of heart disease.

Genes (DNA) determine how your body looks and functions. For example, your genes determine your hair and eye color, how your platelets function, and your risk for diseases. RNA is involved in the building of proteins. We may measure RNA and DNA to help us understand which genes can contribute to risk for heart-related problems. We will compare information from people with true air filters to placebo air filters before and after the study.

You will be randomly assigned to receive either a "true" air cleaner or a "sham" (placebo) air cleaner that is identical to the true air cleaner. You will be given the study equipment and instructions on how/when to use them. This will include an air cleaner (or "sham" air cleaner), an electricity monitor, an air pollution monitor and a blood pressure monitor.

We will schedule a video visit with you to help you set up the equipment in your home, and we will schedule your follow-up visit for the final blood draw and return of study equipment.

2. **Video Visit:**

We will schedule this visit within one week of your baseline blood draw. During this visit, we will video chat with you to help you set up the study equipment in your bedroom. We will help you check your blood pressure and confirm that we receive the results. You will then turn on your air filter and run it 24 hours per day for the next 4 weeks.

Blood pressure monitoring:

You will check your blood pressure yourself at home every morning and night for 4 weeks. The results of these recordings will automatically transmit to a secure database that does not contain any identifying information.

3. Final Visit:

Since we want to test your blood and risk factors for heart disease and stroke before and after using air cleaners, we will draw blood again. No more than 15 ml (≈1 tablespoons and 3% of a standard blood donation) of blood will be collected and stored in tubes. If you have opted in to future research, we will draw an additional 10 mL of blood at the same time. The final visit blood draw will take place either at your doctor's office or another private clinical space at NYU.

You may also be asked to fill out additional questionnaires about your medical history, and update any interim history. Your health will be monitored by review of your medical chart. Additional questionnaires may be administered by phone or during routine clinical follow-up, as appropriate.

At this visit you will return the air pollution monitor, electricity monitor and blood pressure data hub. You will keep the air cleaner and the blood pressure monitor. If you were assigned to the "sham" air cleaner group, you will be given true filters for your air cleaner to keep.

Additional Optional Research - Stored Samples for Future Research

In addition to the main part of the study, there is optional research you may want to participate in.

What is the purpose of this optional part of the study?

We would like to collect and store a small amount of your blood for the purpose of continued analyses of this study, for studies as new scientific discoveries are made, to allow for retesting if necessary and for future research related to cardiovascular risk associated with air pollution. This small amount of additional blood (~10 mL) will be collected at the same time as the blood draw for the main study, so there are no additional risks from this blood collection. This will be done at both the baseline and final visits. Because there are many unknowns about cardiovascular risk, being able to maintain the samples will allow us to build upon the knowledge we gain from this initial study. It is not possible to list every future research project at this time.

The research may include genetic research on the DNA in your samples. DNA is the material that makes up your genes. All living things are made of cells. Genes are the part of the cells that contain the instructions that tells our bodies how to grow and work. They also determine physical characteristics such as hair and eye color. Genes are passed from parent to child.

There are many differences in DNA from one person to another and these differences can affect a person's chance of getting a disease or the way a person responds to a drug. Genetic research studies these differences, which may allow researchers to find new ways to find, treat, and maybe prevent or cure health problems, including heart disease.

If you agree to have your samples stored, you have two options:

1. Samples can be stored for future research and they **can** be used for genetic research.
2. Samples stored can be for future research but they **cannot** be used for genetic research.

How will my samples be used?

Blood samples will be assigned a unique code number and stored without any identifying information other than a code number. The unique code number will not be based on any information that could be used to identify the subject (for example, social security number, initials, birth date, etc.). The master list linking names to code numbers will be kept in a locked file cabinet, separate from all research information placed under double lock and key, and also kept electronically, under double lock and key. Access to the data will be given to the study personnel only. Only the principal investigator and co-investigators will have access to the banked samples. Because the results of this genetic testing is unlikely to show any useable medical information about you, results of genetic testing will not be provided to you or your doctor and will not become part of your medical record.

Identifiers will be removed from the identifiable private biospecimens. After such removal, the biospecimens could be used for future research studies without additional informed consent from the subject. Results of the future research will not be shared with you or your study doctor, and will not become part of the medical records. In general, results from studies that use data collected as part of this research will be preliminary, and the clinical implications of any findings may not be understood for years.

Other institutions or future collaborators at or outside of NYU Medical Center may want to study a portion of these samples, too. If that happens, your samples would be sent to other places so other people interested in studying these diseases and conditions could do that. Because the samples are de-identified and won't have your name or any personal information on it, these other institutions would not know who you are. All samples stored in a secured laboratory in the Cardiology Division Science Building Laboratories will be destroyed no more than 20 years from the end of the study. We think that within 20 years we will have learned significantly more about air pollution and risk of cardiovascular disease.

If you request in writing to the PI, Dr. Jonathan Newman that you wish for these samples to be destroyed earlier, the study team will honor that request and destroy the samples upon your request. His mailing address is NYU Translational Research Building, 227 E. 30th St, Suite 853, NEW YORK 10016. Withdrawing Authorization only affects uses and sharing of information after written request has been received, and subject may not withdraw his/her Authorization for uses or disclosures that have previously been made or must continue to complete analyses or report data from the research.

Do I have to take part in this optional part of the study?

You may decide not to take part. Your blood will not be stored for future research. This decision will not affect your participation in the main study. You will make your selections for optional part of the study at the end of this consent form.

Additional Optional Research – Additional Future Studies

We will also ask you if you would like to be contacted to consider participation in future research studies related to this one. Your answers to this will not affect your participation this current study or other unrelated studies by other investigators.

5. What are the possible risks or discomforts?

There are no known risks of using commercially available air cleaners.

Risks of Blood Collection: You may feel slight discomfort or pain from the blood sampling. A bruise may temporarily form at the site where blood was collected. Rarely, taking blood may cause fainting or infection. The total amount of blood will be about 30 ml for 2 draws (or about 50 if you opt-in to the future research).

Risks of Confidentiality and Genetic Testing: Research that uses information from your medical record can affect your privacy.

Your participation in the research will be held strictly confidential and only coded numbers will be used to identify specimens and research records. We are taking several precautions to protect your privacy and confidentiality including: identifying all blood and data with a code that does not identify you and, storing information on a secure database and only allowing limited personnel to collect data.

Genetic testing can generate information about subjects' personal health risks and can cause or increase anxiety, damage family relationships, and/or compromise insurability, employability and can even lead to discrimination. Confidentiality will be preserved to the fullest extent by the research team. All data will be stored with a unique code that does not identify you. Furthermore, all physical data will also be kept under double physical lock. Access to the data will be given to the study personnel only. The results will not be shared with you or placed in your medical record, thereby greatly reducing the possibility of psychological or social risks that could arise from knowledge of this genetic information, such as risk for your employability or insurability or the risk of discrimination.

There is a new Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Genetic results will NOT be provided to you, any insurance company, any employer, any family member or friend, any of your physicians, or any third party unless required to do so by law.

6. Can I be in the study if I am pregnant or breastfeeding?

There are no known risks to using air cleaners during pregnancy, and may be benefits. However, if you are currently pregnant, you will not be able participate in the study. You should not become pregnant while you are participating in this study. If you are able to become pregnant, you should use a medically accepted method of birth control while you participate in the study, such as:

- Hormonal methods like birth control pills, patches, vaginal rings or implants,
- Barrier methods such as condoms or a diaphragm used with spermicide (a foam, cream or gel that kills sperm),

- Intrauterine device (IUD),
- Abstinence (no sex).

If you become or you think you have become pregnant during the study, you must tell the principal investigator right away and must tell your obstetrician or other health care provider caring for you during your pregnancy that you took part in this study. If you become pregnant, you will have to stop taking part in the study because the study is not designed to test changes in the blood during pregnancy. The principal investigator may ask you to provide information about the outcome of your pregnancy and the health of your baby.

7. What if new information becomes available?

During the course of this study we may find more information that could be important to you.

This includes information that might cause you to change your mind about being in the study. While this is not likely because the risks of being in the study are very low, we will notify you as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

It is possible that some study subjects who receive true air cleaners may experience an improvement in their cardiac risk and blood pressure during the study. However, if you receive such benefit, because portable air cleaners are not FDA-approved for blood pressure or inflammation your doctor cannot prescribe it after you finish the study. Also, you may not get any benefit from being in this research study. Others with high blood pressure may benefit in the future from what we learn in this study.

9. What other choices do I have if I do not participate?

You do not have to participate in this study to receive ongoing or future care.

10. Will I be paid for being in this study?

You will receive reimbursement for transportation or parking costs related to study site visits, as needed. In order to be paid, you must give the receipts to the study staff.

In addition, participants will receive $25 after the baseline visit (blood draw) and $75 for the final visit (blood draw and equipment return) as compensation for their time.

If you complete the study, you will be allowed to keep the air cleaner, and will be given a true filter if you were assigned to the “sham” cleaner group; you will also be allowed to keep the blood pressure monitor. You will receive $75 after all other equipment is returned (electricity monitor, air pollution monitor and blood pressure data hub) and the final blood draw is completed. If you choose to leave or are withdrawn from the study for any reason before finishing the entire study, you will only receive reimbursement for portions you complete.

In order for you to receive a payment check, you need to give the study staff either your Social Security number or your Alien Registration number. If you do not have either of these numbers, you may be in the study but will not receive any payment.

Biospecimens collected for the purposes of this research (even if identifiers are removed) may be used for commercial profit. If your biospecimens are or become commercially profitable, you will not share in this commercial profit.

11. Will I have to pay for anything?

There are no additional costs to you or your health insurance for participation in the study.

12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

If such complications arise, the study doctor will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury-related costs. We will bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for NYU Langone Medical Center or NYU School of Medicine to provide compensation in the event of a study-related injury. You do not give up any rights to seek payment for personal injury by signing this form.

13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected.
This study may also be stopped or your participation ended at any time by your physician or the study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

14. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes

information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: NYU Clinical Translational Science Institute
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 212-263-4110. The NYU Langone Health IRB is made up of: Doctors, nurses, non-scientists, and people from the Community

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Optional Agreements

☐ I agree to be approached/contacted to consider taking part in other studies related to this one.

☐ I do NOT agree to be approached to consider taking part in other studies related to this one.

Stored samples for future research (optional)

Check one below:

☐ I voluntarily agree to have my samples stored for **future research**

☐ I DO NOT agree to have my samples stored for **future research**

Check one below:

☐ I voluntarily agree to have my samples stored for future GENETIC research

☐ I DO NOT agree to have my samples stored for future GENETIC research

I understand that I am entitled to and will be given a copy of this signed Consent Form