Consent Form

NCT07151235

A Controlled Human Environmental Study Evaluating the Impacts of Cognitive Functions during the Exposure of Simulated Wildfire-Related Air Pollution (WRAP).

09/10/2025

RUTGERS
School of Public Health

CONSENT TO TAKE PART IN RESEARCH

Title of Research: A controlled human environmental study evaluating the impacts of cognitive functions during the exposure of simulated Wildfire-Related Air Pollution (WRAP).
Principal Investigator: José Guillermo Cedeño-Laurent, MSc, ScD.

RESEARCH SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this research. It is your choice to take part or not.

PURPOSE: The purpose of this research is to investigate how inhaling pinewood smoke impacts cognitive function (the way we think and solve problems). If you take part in the research, you will be asked to come in for two visits to the Environmental and Occupational Health Sciences Institute (EOHSI). Each visit will last five hours, approximately. The visits will include a questionnaires, online tests, blood samples, urine samples, and two different exposure sessions. One exposure will be to clean air and the other exposure will be to air with pinewood smoke. Your time in the study will take approximately 10 hours.

RISKS/BENEFITS: Possible harms or burdens of taking part in the study may be irritation of the eye, nose or throat, cough or headache after the pinewood exposure but these are expected to be mild and to begin to dissipate within an hour of the exposure. These effects may last four to six hours. There are no direct benefits for taking part in this study.

ALTERNATIVES: An alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Dr. José Guillermo Cedeño-Laurent is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are other individuals who are part of the research team.

Dr. Cedeño-Laurent may be reached at +1 (617) 842-4357 or Rutgers-Environmental and Occupational Health Sciences Institute (EOHSI), 170 Frelinghuysen Road, Piscataway, New Jersey 08854. Phone: (848) 445-0200.

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this research being done?
This study is being conducted to investigate how exposure to pinewood smoke affects cognitive function. Pinewood smoke and other sources of smoke are present during wildfires. Exposure to high concentrations of wildfire-related air pollutants can lead to reduced cognitive performance. These levels may also cause breathing problems, particularly in people with asthma or other diseases. This study will improve the understanding of how breathing wildfire-related air pollutants may affect the brain activity using a non-invasive tool like eye tracking and light-based sensor (fNIRS). The study will also examine

how short-term exposure wildfire smoke may also affect other parts of the body, such as the lungs and the heart.

Who may take part in this research and who may not?
Healthy non-smoker men and women weighing at least 110 pounds between the ages of 18 and 40 may take part in the study.

People with the following conditions may not take part in the study:

- Claustrophobia or not comfortable in enclosed spaces.
- Colorblindness.
- Inability to hear verbal instructions.
- Cardiovascular disease which, in the opinion of the investigator, would elevate the participant's risk of adverse effects to WRAP exposure. This includes a history of stroke.
- Diabetes requiring the use of insulin.
- Pregnancy (A pregnancy test will be provided to you).
- Current asthma (an asthma attack within the past five years).
- History of childhood asthma.
- Medications which may affect cognition such as beta-blockers and CNS depressants.
- Respiratory symptoms in the previous 4 weeks (cough, wheezing, shortness of breath, etc.) which, in the opinion of the investigator, would elevate the participant's risk of adverse effects to WRAP exposure.
- Use of sedating cold/allergy medications in the previous week.
- Use of marijuana in the previous week.
- Consumption of alcohol in the previous 24 hours.
- Kidney or liver disease.
- Thyroid disease.
- High blood pressure.
- Cancer.
- Parkinson's disease.
- Pacemaker.
- Hay fever.

Why have I been asked to take part in this study?
You have been asked to take part in the study because you are a healthy adult who expressed interest in the study.

How long will the research take and how many subjects will take part?
Twelve subjects will participate in the study. Each subject will make 2 visits to the Environmental and Occupational Health Sciences Institute (EOHSI). The visits will take 5 hours each. The total time for the study will be approximately 10 hours.

What will I be asked to do if I take part in this research?
You will be asked to come to EOHSI for 2 visits. At the first study visit, your height and weight will be measured. At each study, you will be asked questions about your recent health (if you've had a cold) and exposures (if you drank/smoked marijuana or used cold medications recently). If you have, your visit may

be rescheduled. At the first visit, you will be randomly assigned to either of the masked clean exposure or the exposure to pinewood smoke.

Visit Activities:
Before exposure (approximately 2 hours)

- Women will be given a urine pregnancy test. If positive, they will be ineligible to continue with the study.
- You will be asked to complete a short 5-minute survey about any general health status
- You will be asked to wear a portable heart monitor during the entire visit.
- Your blood will be drawn (20 ml) and your urine collected (10 ml).
- You will be asked to wear a headset that measures blood flow and oxygen levels in your head.

During exposure: (approximately 0.5 hours inside the cabin before a 1 hour exposure)

- You will then be taken the experimental room where you will entered a phone-booth like chamber and you will be exposed to either clean air or pinewood smoke. The exposure session inside the cabin will last approximately 1 hour.
- While you are in the booth, you will be asked to complete a series of cognitive tests on a laptop. One series of cognitive tests will be before exposure begins, and another series at 20 minutes after the beginning of the exposure.

Immediately after exposure (0.5 hours)

- The headset measuring blood flow will be removed.
- The heart rate monitor will be removed.
  Your blood will be drawn (20 ml) and your urine collected (10 ml).
- You may leave the lab but will be asked to return 4 hours later to complete the study.
- The heart rate monitor will be removed.

After the exposure (approximately 0.5 hours)

- You will be asked to complete a series of cognitive tests on a laptop.
- Your blood will be drawn (20 ml) and your urine collected (10 ml).

What are the risks of harm or discomforts I might experience if I take part in this research?

1. Exposure to pinewood smoke may cause temporary symptoms including cognitive deficit, irritation of the eyes, nose or throat, cough or headache but these are expected to be mild and to begin to dissipate within an hour of the exposure. These effects may last up to six hours. If the symptoms are severe or cause you concern, you will be seen by a physician at the EOHSI clinical center for treatment/referral.
   Pinewood smoke is primarily composed of three regulated pollutants:

- **Carbon monoxide and carbon dioxide:** When participating, you may be exposed to low levels of carbon monoxide (CO) and carbon dioxide (CO_2), which can sometimes cause mild discomfort. Carbon monoxide is a gas that, even at low levels, can cause symptoms like headaches, dizziness, nausea, tiredness, or confusion—symptoms that might be mistaken for the flu. These

effects depend on how much CO you breathe in, for how long, and your health. For example, healthy people might just feel tired at low levels, while people with heart problems could experience chest pain. Very high CO levels can cause serious problems like trouble seeing, poor coordination, unconsciousness, or worse, but in this study, expected CO levels are much lower than safety limits (between 0.8 and 1.9 parts per million, ppm), so serious effects are unlikely. Carbon dioxide is a natural gas we all breathe out, and it's usually around 400–500 ppm outside. Indoors, if CO_2 builds up to about 1,000–2,000 ppm, some people may feel headaches, tiredness, or have trouble concentrating. Higher levels (above 2,000 ppm) can cause dizziness, sleepiness, or mental fogginess, and very high levels over 5,000 ppm can be dangerous. In this setting, CO_2 levels are expected to stay between 800 and 1,200 ppm, which is below workplace safety limits and similar to recommendations for good indoor air quality, so discomfort is unlikely. Overall, the exposures in this study are well below the levels known to cause harm, but you might notice mild symptoms if you are particularly sensitive.

- **$PM_{2.5}$: Particulate matter with a 2.5 micrometer size**— are tiny particles in the air that can be harmful to your health. Breathing in high levels of $PM_{2.5}$, especially over long periods, can cause eye, nose, and throat irritation, make asthma worse, and reduce lung function. Over time, it can lead to more serious health problems like heart disease, stroke, COPD (a lung disease), and even early death—especially in children, older adults, or people with heart or lung conditions. To protect people, government agencies set limits for safe air quality:
    - The EPA allows up to 12 micrograms per cubic meter (μg/m³) on average over a year, and 35 μg/m³ over a 24-hour period.
    - The World Health Organization (WHO) recommends even lower limits: 5 μg/m³ (annual) and 15 μg/m³ (daily).

  The expected exposure in this study while high (300 μg/m³) is very short-lived and will not likely make you exceed your exposure above the 35 μg/m³ for over a 24-hour period. This exposure level was selected to reflect real world exposure levels during wildfires such as the Los Angeles wildfire in January 2025 during which $PM_{2.5}$ levels spiked over 400 ug/m³.

2. **Venipuncture**: When your blood is drawn, there may be a bruise, bleeding, or infection at the place where your blood is drawn. However, infection is rare.

3. **Risk of Harm from an Intervention on a Subject with an Existing Condition**: The study will not enroll subjects with existing conditions

4. **Other Foreseeable Risks of Harm**: There is a risk of possible loss of confidentiality, but no sensitive information is collected in the study.

Are there any benefits to me if I choose to take part in this research?
You will receive no direct benefit of taking part in the study. Your participation will help scientists better understand how cognitive function changes when exposed to pinewood smoke.

What are my alternatives if I do not want to take part in this research?
Your alternative is not to take part in this research.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the research, you will be updated about any new information that may affect whether you are willing to continue taking part in the research. If new information is learned that may affect you after the research or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
Participants will be mailed clinical results from the blood sample collected at the first visit. However, individual results from the study will not be given. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Will there be any cost to me to take part in this study?
There will be no cost for you to participate in this research.

Will I be paid to take part in this study?
You will be paid in cash, up to $300 to take part in the study. You will be paid according to the visits you complete:

- Visit 1: $150.00
- Visit 2: $150.00

Each time you receive the payment you will sign a receipt with the amount of money given to you.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. By taking part in this study, you should understand that the study collects demographic data and data on your health. This data will be recorded by the study doctor/investigator who may store and process your data with electronic data processing systems. The data will be kept as long as the study is being conducted and for 6 years after.

Your personal identity, that is your name, address, and other identifiers, will be kept confidential. You will have a code number and your actual full name will not be used on questionnaires and related data. Only your study doctor and designated research study staff will be able to link the code number to your name and will keep this information during the study. When the study is finished, the link will be destroyed.

Your data may be used in scientific publications. If the findings from the study are published, you will not be identified by name. Your identity will be kept confidential.

The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Officials at Rutgers University
- Department of Health and Human Services – government agency that oversees and funds research involving human beings

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

What will happen to my information—data, recordings and/or images—and bio-specimens collected for this research after the research is over?

After information that could identify you has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional informed consent from you.
Specimens sent to our chosen laboratories will be destroyed after all data have been reviewed and approved. Remaining specimens will be stored indefinitely for use only by the study investigators. The link between the study ID and the subject identity will be destroyed when the study is closed.

What will happen if I am injured during this study?
Subjects in this study will be exposed to certain risks of personal injury, which include exposure to high levels $PM_{2.5}$, moderate levels of CO_2 and low levels of CO. In addition, it is possible that during the course of this research, new adverse effects related to the respiratory system that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.
You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to José Guillermo Cedeño-Laurent, 170 Frelinghuysen Road, Piscataway, New Jersey 08854.

Who can I contact if I have questions?
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator:

José Guillermo Cedeño-Laurent
Rutgers School of Public Health
+1 (848)-4450-190

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

Permission to Contact You with Additional Requests to Participate in Research

Please tell us if we may contact you in the future to tell you about other ways you may participate in this research or other research we are conducting by initialing next to your choice.

The investigators may contact me in the future to ask me to take part in more research.

Yes ____ No _____

Thank you for considering participation in this research.

AGREEMENT TO TAKE PART IN RESEARCH

Participant Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this research have been answered. I agree to take part in this research.

Participant Name (Print):_____

Participate Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the research including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____